UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

MONSANTO COMPANY and MONSANTO TECHNOLOGY LLC,	)	
Plaintiffs,	)	
vs.	)	
E.I. DUPONT DE NEMOURS AND COMPANY and PIONEER HI-BRED INTERNATIONAL, INC.,	)	Case No. 4:09-cv-686 ERW
Defendants.	)	

MONSANTO'S RESPONSE TO DEFENDANTS' CLAIM CONSTRUCTION BRIEF

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INTRODUCTION

The '247 patent describes a groundbreaking biotechnology invention, and its claims reflect the breadth of that invention. By their express terms, they cover (1) novel *DNA molecules* with the genetic code for Class II EPSPS enzymes; (2) *transgenic plants, plant cells, and seeds* that are tolerant to the herbicide glyphosate due at least to these DNA molecules; and (3) *methods for controlling weeds* using those transgenic plants and seeds. Individually and collectively, these claims cover Monsanto's Roundup Ready® soybeans and corn. Defendants know this. They have paid Monsanto hundreds of millions to license Roundup Ready® under the '247 and '435 patents – not out of generosity, but because they were compelled to do so having failed to develop competitive products on their own. Clearly, companies of DuPont or Pioneer's sophistication do not pay their competitors huge sums to license invalid or nonessential patents that they do not practice.

It is only now – caught red-handed in breach of their license – that Defendants purport to interpret the claims to *exclude* Monsanto's own Roundup Ready® technology. Abandoning the claim construction that underpinned their summary judgment motion based on supposed patent "broadening," Defendants now pursue constructions so extreme and so narrow that they give the claims virtually no scope. Defendants import literally *paragraphs* of excess verbiage into the claims from the specification, extrinsic sources, or thin air. In attempted support, they submit 45 pages of briefing, 186 tiny footnotes, 2 extrinsic declarations, 61 exhibits, and an additional 77 pages of argumentative "appendices" – which misstate the law and the record many times – all in an attempt to convince the Court the '247 patent's claims do not actually mean what they say.

The result of Defendants' efforts are constructions that bear no resemblance to the claim language, and fundamentally alter the character of the invention. First, Defendants request that the Court construe facially clear claims to DNA molecules as requiring an "***active process***" that

produces an EPSPS enzyme with an "***exact***" amino acid sequence and "***efficient***" enzyme kinetics. Yet, a claim to a DNA molecule (a chemical compound patentable as a composition of matter) is dramatically different than a claim to an "active process" of making a particular enzyme. The claims recite DNA molecules, *not* processes. It is error to construe them otherwise.

Second, Defendants interpret the claims to "glyphosate tolerant" plant cells, plants, and seeds to additionally require that the resulting plant be *unharmed* by the application of glyphosate herbicide that typically kills a non-transgenic plant. The '247 patent, however, contains numerous examples of plants that it calls "glyphosate tolerant" that were damaged by glyphosate, but exhibited tolerance relative to non-transgenic, control plants. Even the progenitor to Monsanto's Roundup Ready® soybeans, described in Example 3, exhibited *some* damage to glyphosate. The claims must be read to cover what is described in the patent.

Third, Defendants ask this Court to limit the claims to weed control to the point of non-existence. Defendants propose that these claims require that the glyphosate kill every single weed in a field (which can be acres in breadth), yet leave all of the transformed crops totally unharmed. The patent claims, however, do not require perfection. By their express terms, they require only "*controlling*" the weeds with glyphosate "without *significantly* affecting the crop." Limiting the claimed methods to perfectly unharmed plants and perfectly dead weeds again ignores the totality of the patent's examples and written description.

Try as they might, Defendants' arguments and distractions cannot change the plain meaning of the asserted claims. The Court should give meaning to the language as they were *actually drafted*, in light of the intrinsic evidence, not as Defendants wish they were drafted. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313-14 (Fed. Cir. 2005) (en banc). Likewise, the court "will not at any time import limitations from the specification into the claims." *Innogenetics,*

N.V. v. Abbott Labs., 512 F.3d 1363, 1370 (Fed. Cir. 2008). And, as a matter of law, the claims cannot be construed to exclude the patent's preferred embodiments. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996) (holding that a construction that excludes a preferred embodiment is "rarely, if ever, correct.").

For all of these reasons, and many others, Defendants' proposed constructions should be rejected. The asserted claims undeniably cover the DNA molecules, plants, plant cells, seeds, and methods that comprise the Roundup Ready® technology described in the specification, which Defendants misappropriate through their unlicensed, stacked products. The Court should adopt Monsanto's proposed constructions – the only ones consistent with the actual claim language and the intrinsic evidence.

ARGUMENT

In their claim construction papers, Defendants propose that this Court construe a total of thirty-seven claim terms, including common words ("seed," "cell," "plant," "weed," "crop"), transitional phrases ("having"), and fifteen amino acid or DNA sequences that are set forth in the '247 patent, which Defendants qualitatively interpret in their "Appendix A." Defendants fracture the claims into small pieces, construe each piece out of context, and proceed to import numerous additional limitations into each of the fractured claim pieces they construe. By doing so, Defendants reach constructions that are self-contradictory, contrary to the language of the claims as a whole, and incongruent with the remarkable invention described in the patent.

Many of the claim terms Defendants propose for construction should not even be construed – including the claim preambles and words such as "seed" that a jury would fully understand without further elucidation by Defendants. Nevertheless, Monsanto responds in the sections below, reassembling the fractured claim terms in the context of the claims in which they

appear, and in the general order addressed in Monsanto's opening Claim Construction Brief. The sections begin with claims to DNA molecules, proceed to the claims to transgenic plants, plant cells and seeds, and conclude with the methods of weed control. Miscellaneous terms and other issues Defendants have raised are addressed in the final section.[1]

I. The Claims to "Isolated DNA Molecules" and "Recombinant DNA Molecules" Cover *DNA Molecules,* Not Active Processes or Particular Enzymes

The first category of asserted claims covers DNA molecules that contain the genetic code for Class II EPSPS enzymes. Contrary to Defendants' attempts to obfuscate these claims, they are clear in light of the patent specification. The first set (claims 1-2) covers "isolated DNA molecules" that have been removed from their natural bacterial sources, and exist separately from them. The second set (claims 103, 131, and dependents) covers "recombinant" DNA molecules that contain additional elements representing the minimum structural requirements for the DNA molecules to function in a plant cell. These claims to isolated and recombinant DNA molecules are patentable on the same basis as other chemical compounds, *see Amgen, Inc. v. Chugai Pharm. Co., Ltd*., 927 F.2d 1200, 1206 (Fed. Cir. 1991), as "composition[s] of matter" under 35 U.S.C. § 101. The claims do not have process limitations or limitations on their use.

Defendants' construction of these claims fails on many levels. Defendants unreasonably construe them to *exclude* plant cells containing the DNA molecules (Dkt. 243 at 9), erroneously require an "active process" of producing an EPSPS enzyme of "a particular sequence" (*Id.* at 26), and furthermore, render the claims internally inconsistent. Defendants require an "isolated DNA molecule" be purified and alone, yet simultaneously be producing particular enzymes – a

[1] Initially, Defendants contend (without support) that the asserted claims are only entitled to claim priority to a 1994 filing date. (Dkt 243 at 1). Their gratuitous statement is wrong and irrelevant to claim construction. "[W]hether the written description in the priority applications is adequate to entitle a later-issued patent to the benefit of an earlier filing date is a separate legal issue from claim construction, and is to be analyzed separately *after* the claims have been construed." *Nextec Applications v. Brookwood Co., Inc*., __ F. Supp. 2d __, 2010 WL 1257447, at *35 n.28 (S.D.N.Y., Mar. 31, 2010) (emphasis added).

feat that is not *possible* if the DNA is purified and alone. Likewise, Defendants *exclude* the recombinant molecules from being in a plant cell (*id.* at 9), but *require* them to actively "function in *every* plant cell." (*E.g.*, *id.* at 19).

Defendants' constructions import numerous limitations that turn these pure compound claims into something that is neither fish nor foul, but a strange chimera that is a DNA molecule, an "active process," and an "exact" "kinetically efficient" enzyme all rolled into one. Monsanto's straightforward constructions are clearly the correct ones.

A. The Claims to "Isolated DNA Molecules"

1. An isolated DNA molecule which encodes an EPSPS enzyme having the sequence of SEQ ID NO:3.
2. **[A]** *The* DNA molecule of claim 1 having the sequence of SEQ ID NO:2.

The two claims to "isolated" DNA molecules – independent claim 1 and dependent claim 2 – recite DNA molecules containing the genetic code for an EPSPS enzyme with the amino acid sequence of SEQ ID NO:3 (the sequence of the CP4 bacterial protein). Claim 1 covers the *genus* of DNA compounds encoding SEQ ID NO:3, while claim 2 recites the *particular* DNA sequence (SEQ ID NO:2 – a nucleotide sequence) isolated from the CP4 bacterium. The parties' disputes relate to Defendants' improper efforts to impose limitations onto the claims excluding them from existing in a plant cell, and limiting them to an "active process" of producing an enzyme of exact amino acid sequence and specific kinetic properties.

1. An "Isolated DNA Molecule" Means a DNA Molecule Separated from Its Natural Source, Not Purified in a Test Tube

Claim Term	Monsanto's Construction	Defendants' Construction
An "isolated DNA molecule"	"A DNA molecule existing separately from its natural source."	"A DNA molecule that is separated from other molecular species of a cell in the form of a purified DNA fragment" (Dkt. 243 at 11).

Properly construed, the term "isolated" simply refers to the fact the DNA molecule was removed from its natural host and exists apart from it. Defendants, however, in an effort to create a non-infringement defense, attempt to drastically limit the claim by importing extraneous limitations requiring the DNA to be a "*purified* DNA *fragment*" that is "*separated from other molecular species of a cell*," (Dkt. 243 at 11), and is confined to a "*test tube*" (*id.* at 8). Thus, Defendants assert, the DNA cannot be included in a plant cell. Defendants are dead wrong.

Defendants' additions do not appear in the claim language, nor are they supported by the specification. The usage Defendants acknowledge in their brief supports *Monsanto's* construction. It provides that "[g]enes coding for Class II EPSPS enzymes have been *isolated from* five (5) different bacteria." (*id.* at 12) (quoting 3:58-59[2]) (emphasis added). This says nothing about the genes being "purified" or being "fragments" or being in a "test tube." It refers to the fact that the genes coding for these enzymes were obtained from a natural source, and through the inventors' intervention, now exist in a usable state existing separately from it.

Nothing in the specification indicates that the inventors intended to preclude the claims to "isolated DNA molecules" from covering plant cells containing that isolated DNA. The whole point of the invention is to use the isolated DNA in transformed cells to confer glyphosate tolerance (*see, e.g.*, Abstract), and the patent uses the term "isolated" DNA in the context of combining the "isolated DNA" with other molecular species, such as in vectors and in transformed cells. (Opening Br., Dkt. 259 at 17-18) (citing 7:60-68, 8:48-53, and 32:16-17).

Nor does the plain meaning of the term "isolated" exclude the DNA from being in plant cells, as Defendants suggest. (Dkt. 243 at 12). The patent uses the term "isolated" to refer to DNA molecules that are isolated *with respect to* their natural source. (*E.g.*, 41:67-42:2 ("The

[2] Citations in this format refer to the column and line numbers 7of the '247 patent, Dkt. 259-2. Citations to "Dellaporta" or "Dellaporta Decl." refer to the Rebuttal Declaration of Dr. Stephen L. Dellaporta, filed concurrently herewith.

EPSPS gene was isolated originally *from* Agrobacterium sp. strain CP4 and expresses a highly tolerant enzyme."); *id.* at 30:20 ("Intact chloroplasts are isolated *from* lettuce")). In that sense, the patent is entirely consistent with the one dictionary definition that Defendants cite. The DNA claimed in claim 1 *has* been "set or place[d] apart" and "detach[ed] and separate[d]" from the CP4 bacteria that was its natural host. The patent does not use the term "isolated" in an absolute sense requiring the DNA to be purified from all other things. Had the inventors wanted for some reason to claim a purified DNA fragment isolated from the rest of the universe, they would have included that type of limitation in the claim. They did not, because there was no need to do so.

The patent's usage of "isolated" is consistent with Defendants' own patent claims, which allow the "isolated" DNA to be in plant cells or plants (Dkt. 259 at 19 (discussing Ex. 4-5)), and in the claims to myriad others, which use that term to exclude the naturally occurring source of the gene. (*See id.* at 18). For instance, as Defendants recognize, the patent this Court construed in *DeKalb Genetics Corp. v. Syngenta Seeds, Inc*. claimed the "isolated" DNA molecule *within* the transgenic maize plant. 2007 WL 4564196, at *11 (E.D. Mo. Dec. 21, 2007).[3]

Defendants argue, however, that an "isolated DNA molecule" must be excluded from a plant cell in *this* case, because "Claim 1 lacks any elements that indicate the isolated molecule would be present in a plant cell." (Dkt. 243 at 11). Yet, as Defendants themselves have explained: "Under black-letter patent law, the more limitations included in a claim, the narrower it is." (Dkt. 216, at 3). Because claim 1 contains no limitation *requiring* the DNA to be in a plant cell, it covers the isolated molecule *regardless* of whether it is inside or outside a plant cell. Defendants likewise misunderstand the prosecution history by relying on the Examiner's statement that there is "no limitation" in the claim directed to isolated DNA "which indicates

[3] *See also Intervet Inc. v. Merial Ltd.*, No. 2009-1568, Slip. Op. at 5-6 (Fed. Cir., Aug. 4, 2010) (attached as Exhibit 1) (construing patent claiming "a vector comprising an *isolated* DNA molecule….")

modification for use in plant cell." (Dkt. 243 at 11 n.31) (emphasis added). That there is no such *limitation* simply means that the claim is *broader* than it would be if it required the isolated molecule to be in a plant cell. A claim need not *require* something to *cover* it.

Recognizing the lack of intrinsic evidence to support their construction, Defendants purport to rely on two articles that use the word "purified" to describe biological materials. (*Id.* at 12). The papers Defendants rely on (cited among the 100+ references in the patent) do not even begin to support their position. Each contains sentences saying that an *enzyme* was "purified." They say nothing about the meaning of "isolated" at all, much less in the context of the '247 patent's claims. (Dellaporta Decl., ¶¶ 12-16). That Defendants scour such sources – and come up empty handed – indicates there is no support anywhere for their construction.

Defendants also attempt to support their construction by badly misstating arguments Monsanto made in the *Trivette* litigation. Starting their quotation in mid-sentence, and using ellipses to omit all of the context, Defendants assert Monsanto contended that "isolated" DNA means "it's sitting in a test tube in the laboratory as an actual molecule . . . . That's what 'isolated' means." (Dkt. 243 at 13). In reality, Monsanto's counsel explained that "isolated" distinguished the claims from a natural source. She specifically stated, and the Court understood, that the "isolated DNA molecule" covers seeds containing the isolated molecule:

> THE COURT: Actually, it's an isolated DNA molecule. Explain what that means.
>
> MS. KNOLL: That has a meaning in the art of biotechnology and science***. That's to distinguish a DNA molecule that is actually already existing in nature.*** This means it's been genetically engineered and uses recombinant DNA to take it out, so it's actually sitting in a test tube in the laboratory as an actual molecule, not something that's just existing in the cauliflower mosaic virus as it exists in nature. ***So it gets to some of the basic, very fundamental aspects of patenting DNA, which goes back to say you have to differentiate it, there has to be some man-made intervention, has to be differentiated in some way from that which is already existing in nature. That's what the "isolated" means***.

> THE COURT: Now I understand. ***This isolated DNA molecule is, you say, in the Roundup Ready seeds.***
>
> MS. KNOLL: ***Yes, ma'am.***

(Dkt. 112-6 at 54-55; *see id.* at 58 ("It means it's man-made, or a man-made component to it.")). That Defendants were required to selectively edit and mischaracterize what was actually said is telling. The transcript fully ***supports*** Monsanto's claim construction.

Finally, Defendants stretch to rely on an English court's interpretation of the term "isolated," in a different patent, under foreign law. Defendants recognize that the decision is obviously "not binding on United States District Courts," but suggest this Court should adopt that decision because the Federal Circuit purportedly said that district courts should consult foreign courts "[i]n the interests of uniformity and correctness." (Dkt. 243 at 13). That is not true. In the case Defendants cite, the court actually said: "In the interest of uniformity and correctness, this court consults the claim analysis of different ***district courts*** on the ***identical terms*** in the context of ***the same patent***." *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1329 (Fed. Cir. 2008) (emphasis added). The foreign decision, which does not address the meaning of "isolated" under U.S. law, has no relevance here.

Under U.S. law, the term "isolated" is consistently used in patent claims to provide broad coverage to the DNA molecule that excludes only the natural host of the molecule. (Opening Br., Dkt. 259, at 18-19).[4] Here, like in DuPont's own patents, the patent in *DeKalb*, and many

[4] The term "isolated" operates as a "negative" limitation in DNA claims, like the term "non-naturally occurring." *See Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1329 (Fed. Cir. 2003) (noting "the 'non-naturally occurring' limitation in claims 3 and 4 merely prevents Amgen from claiming the human EPO produced in the natural course. By limiting its claims in this way Amgen simply avoids claiming specific subject matter that would be unpatentable under § 101. This court has endorsed this approach, recognizing that patentees can use negative limitations such as 'non-human' and 'non-natural' to avoid rejection under § 101.").

others, there was no reason for the inventors to have placed artificial restrictions on the claim to exclude coverage of the isolated DNA molecule in plants. They did not do so.

2. "Encoding" Refers to the Genetic Content of the DNA, Not an "Active Process" of Gene Expression

Claim Term	Monsanto's Construction	Defendants' Construction
"which ***encodes*** an EPSPS enzyme having the sequence of SEQ ID NO:3"	"A DNA molecule that 'encodes' a protein means that it contains the genetic code for the specified protein."	Encodes refers to "the active process of using the instructions within the genetic material to produce a glyphosate-tolerant EPSPS enzyme of a particular sequence." (Dkt. 243 at 26). EPSPS enzyme means "a kinetically efficient EPSPS enzyme such that when introduced into a plant the catalytic activity of the enzyme and plant metabolism are maintained in a substantially normal state with minimal expression of the enzyme while still conferring glyphosate tolerance to the plant." (*Id.* at 30).

The term "encodes," which appears in claim 1 and every other asserted claim, defines the informational content, and thus the chemical structure, of the claimed DNA molecules. In the case of claim 1, the phrase "which *encodes* an EPSPS enzyme having the sequence of SEQ ID NO:3" defines a genus of DNA molecules containing the genetic code for an enzyme of that amino acid sequence. Defendants, however, misread the claim to require the "active process" of making a specific, "kinetically efficient" enzyme that has an "exact" amino acid sequence, and certain "catalytic activity" – despite the fact that none of these requirements appears in the claim.

A claim to a DNA molecule is a claim to a chemical compound. *Amgen, Inc.*, 927 F.2d at 1206. Where the claim specifies that the DNA molecule *encodes* a protein of a certain amino acid sequence, the amino acid sequence defines the sequence of DNA molecules that encode it. For example, in *In re Kubin*, the Federal Circuit held a claim to "an isolated nucleotide sequence encoding a polypeptide" was a claim to "a genus of polynucleotides." 561 F.3d 1351, 1353, 1356 (Fed. Cir. 2009); *id.* at 1356 ("Appellants claim a gene sequence"). Likewise, the '247 specification uses the term "encodes" to mean that the DNA molecules contains the informational content of the specified amino acid sequence. (Opening Br., Dkt. 259, at 18-20).

The term "encoding" does not mean an "active process," and that is not how it is used in the patent. When the specification refers to a biological process, it typically uses the term "expression," which can refer either to transcription or translation, depending on its context. (*See e.g.*, 7:33-39 (defining "expression of a plant gene" to mean transcription and processing in the nucleus)). Indeed, the patent distinguishes the concept of genes encoding proteins from the production of proteins. It states, for example, that a "transgenic plant in general ***expresses*** the protein ***encoded*** by the inserted gene," and thus establishes the distinction between the two concepts. (8:36-37).

The Federal Circuit has made clear that a claim to a chemical compound is not limited by a process, unless there is compelling evidence in the specification to the contrary. For example, in *Amgen Inc.*, the court held it was erroneous to limit a claim to a DNA compound according to a process. 314 F.3d at 1329; *see also 3M Innovative Props. Co. v. Avery Dennison Corp.*, 350 F.3d 1365, 1371-72 (Fed. Cir. 2003) (refusing to construe product claim to have process element). This rule makes sense, because under 35 U.S.C. § 101, compositions of matter and processes are patentably distinct, and the lines between these types of claims should not be blurred unless the inventors expressed a manifest intent to do so.

In this light, Defendants' suggestion that the words "EPSPS enzyme" require the production of a "kinetically efficient" enzyme with particular catalytic properties is absurd. Within the context of claim 1, these two words are simply part of the same phrase – "which encodes an EPSPS enzyme having the sequence of SEQ ID NO:3" – that defines the informational content of the DNA sequence. The "EPSPS enzyme" referenced in the claim is fully defined by the amino acid sequence of SEQ ID NO:3.

Due to the redundancy of the genetic code, "there are many possible DNA sequences which may code for a particular amino acid sequence." (3:28-29). Indeed, many millions of DNA sequences encode an EPSPS enzyme with the sequence of SEQ ID NO:3. Rather than separately list these sequences in a patent application millions of pages long, Monsanto's inventors defined the genus of DNA molecules in claim 1 according to the established correlation between the amino acid sequence of the EPSPS enzyme and DNA encoding it. Legally, this was entirely appropriate. *See In re Wallach*, 378 F.3d 1330, 1334 (Fed. Cir. 2004) (stating there is "no reason to require a patent applicant to list every possible permutation of the nucleic acid sequences that can encode a particular protein for which the amino acid sequence is disclosed"; it is "a routine matter to convert back and forth between an amino acid sequence and the sequences of the nucleic acid molecules that can encode it.")

There are very good reasons why the inventors claimed the DNA sequence and not the process of making a particular protein. Defendants' own expert submits that RNA "[t]ranscription does not always proceed as it should in theory, nor does it always produce a perfect copy" of the DNA. (Jacobsen Decl., Dkt. 257, ¶ 41). Likewise, "errors can also occur during translation, which can for example result in a truncated protein that does not reach its proper length or a mistake in the amino acid sequence." (*Id.* at ¶ 46). Following translation, a chloroplast transit peptide is cleaved from the EPSPS protein, resulting in potential further modifications. (*Id.* at ¶ 48; 3:36-40). It is unreasonable to require inventors of DNA molecules to claim the precise fates of the claimed DNA molecule *in vivo* when utilized by an infringer. By seeking and receiving claims to the DNA molecules themselves, the inventors received patent protection for their discovery without regard to these downstream processes.

The patent itself does not specifically describe an "active process" of producing an EPSPS enzyme of a particular amino acid sequence; the inventors did not directly sequence an EPSPS enzyme produced by the claimed DNA. The inventors *predicted* the amino acid sequence of the ultimate EPSPS enzyme based on the DNA sequence they had isolated, according to the universal genetic code. (*E.g.*, 6:52-56). Defendants, by proposing a construction that requires an "active process" and a post-processing end-product, seek to deliberately exclude from the claims the DNA molecules that were *actually invented*. This is contrary to the most basic principles of claim construction. *See Phillips*, 415 F.3d at 1321 (discussing the principle that the claims cover the "invented subject matter").

Finally, Defendants' construction is inconsistent with their own interpretation of the remainder of claim 1. Defendants construe "isolated" to be apart from a cell capable of making a protein. Yet, their construction of "encodes" requires the "active processes of transcribing DNA, translating RNA, and completion of downstream post-translational processes" ***which occur in cells***. (Dkt. 257 at ¶ 136). It is not possible for purified DNA alone in a test tube to spontaneously make an EPSPS enzyme. (Dellaporta Decl., ¶ 18). Further, Defendants' construction of the words "EPSPS enzyme" requires a "kinetically efficient EPSPS enzyme ***such that when introduced into a plant*** the catalytic activity of the enzyme and plant metabolism are maintained in a substantially normal state . . . ." (Dkt. 243 at 30) (emphasis added). Defendants' construction thus requires that the claimed DNA be *in a cell* and *not in a cell* simultaneously.

Defendants ignore these self-contradictions, but the Court should not. Because "proper claim construction . . . demands interpretation of the *entire claim* in context," *Pause Tech., LLC v. Tivo Inc.*, 419 F.3d 1326, 1331 (Fed. Cir. 2005) (emphasis added), Defendants' inability to

posit a coherent construction of the claim as a whole demonstrates their litigation position *must* be wrong. And it is.

B. The Claims to Recombinant DNA Molecules.

103. A recombinant, double-stranded DNA molecule comprising in sequence: a) ***a promoter*** which functions in plant cells to cause the production of an RNA sequence; b) ***a structural DNA sequence*** that causes the production of an RNA sequence which encodes an EPSPS enzyme having the sequence of SEQ ID NO: 70; and c) ***a 3' non-translated region*** that functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3' end of the RNA sequence; where the promoter is ***heterologous with respect to the structural DNA sequence*** and ***adapted to cause sufficient expression of the encoded EPSPS enzyme*** to enhance the glyphosate tolerance of a plant cell transformed with the DNA molecule.

The parties' disputes on the claims to recombinant DNA (claims 103 and 131) stem from Defendants' continuing attempts to overload the claims with extraneous language.

1. The Phrase "Recombinant, Double-Stranded DNA Molecule" is a Claim Preamble, Not a Claim Limitation.

Claim Term	Monsanto's Construction	Defendants' Construction
"Recombinant, double stranded DNA molecule comprising in sequence"	Should not be construed. To the extent it is a limitation, it means: "A genetically engineered DNA molecule containing the recited elements in its sequence"	A DNA molecule in a laboratory that is constructed by genetic engineering from at least the three distinct DNA sequence components identified in the remaining part of the claim. The recited component DNA sequences are arranged in the exact order as specified in the claim.

Defendants initially seek to use the preamble of claims 103 and 131 as a vehicle to limit the claim scope. They require the recombinant DNA molecule specified in the preamble be "*in a laboratory*" and "*constructed by genetic engineering from at least the three distinct sequence components identified in the remaining part of the claim*." (Dkt. 243 at 14). Defendants further require it be *excluded* from a plant cell because, purportedly, "[u]pon transformation that DNA is no longer isolated or recombinant." (*Id.* at 8). Finally, they misconstrue the words "comprising in sequence" to require a specific arrangement of component sequences "in the *exact order* as specified in the claim." (*Id.* at 14). Defendants' constructions are obviously wrong.

A "preamble is construed as a limitation if it recites *essential structure* or steps, or if it is necessary to give life, meaning, and vitality to the claim," but it is *not* a limitation "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." *Symantec Corp. v. Computer Assocs. Int'l, Inc.*, 522 F.3d 1279, 1288 (Fed. Cir. 2008) (quotations omitted). "[I]n general, the purpose of a claim preamble is *to give context* for what is being described in the body of the claim; *if it is reasonably susceptible to being construed to be merely duplicative* of the limitations in the body of the claim (and was not clearly added to overcome a rejection), *we do not construe it to be a separate limitation*." *Id.* at 1288-89 (emphasis added).

Under this standard, the preamble of claim 103 and 131 is not a limitation needing construction. The term "recombinant" refers to the fact that a DNA molecule was engineered, in the broadest sense, by human intervention. (Dkt. 267-6). It reflects the claim body, including the requirement of a "heterologous" promoter. Both parties agree that "heterologous" means the promoter comes from a different source than the structural DNA. (Dkt. 243 at 19). Thus, by definition, a gene construct with a "heterologous" promoter is "recombinant," because it is derived from a different source than the structural gene. The preamble simply gives context for the claim by making clear that it covers an artificial DNA molecule.[5]

Contrary to Defendants' erroneous assertion, the language "double-stranded DNA molecule" does not recite any additional structure beyond what is stated in the claim's body.

[5] Defendants contend that the inclusion of the word "recombinant" in the body of *other claims* (i.e., the methods of weed control) make that word a limitation in claims 103 and 131, where it appears only in the preamble. (Dkt. 243 at 14). Neither of Defendants' cases support that proposition. *In Sun Microsystems, Inc. v. Network Appliance, Inc.*, the preamble was a limitation because it was used to distinguish prior art. 591 F. Supp. 2d 1069, 1076-77 (N.D. Cal. 2008). In *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, the preamble was necessary to give meaning to elements in the claim body. 182 F.3d 1298, 1306 (Fed. Cir. 1999). Here, moreover, the word "recombinant" appears in the weed control claims in the same *introductory* fashion as in claim 103 and 131 – not as a separate structural element of the claim.

DNA *is* a double-stranded molecule. By definition, the promoter, "structural DNA sequence," and "3′ NTR" elements of the claim body are double-stranded. (Dellaporta Decl. at ¶ 24).

The final words of the preamble – "comprising in sequence" – indicate that the claimed DNA molecule, comprises the recited elements in its sequence. The word "sequence" appears over 200 times in the '247 patent, and each time it refers to a nucleotide or amino acid sequence. Indeed, it appears later in the same claim in the phrase "a structural DNA sequence," and Defendants construe that term to be "a sequence *of bases*." (Dkt. 243 at 25). It would be anomalous to construe "sequence" in the *preamble* differently than the same term used in the *claim body*. In any event, to the extent that the preamble is construed to require the elements appear in an order, it must be understood to allow for additional elements. By law, the term "comprising" is open-ended (*see infra*, Part IV.B.1), and the patent identifies other elements contained within the DNA molecule, such as a 5′ leader sequence (*see* 9:14-17) and a chloroplast transit peptide (expressly recited in dependent claim 104).

Thus, the preamble simply provides context for the remainder of the claim. Even if it were to be construed, the preamble would never require an "exact order," nor would it require all three of the recited elements to be "in a laboratory," or constructed in a particular way,[6] nor would the claim *exclude* the DNA molecule from plant cells – the very point of the invention. Those phony limitations are present nowhere in the claim preamble, either expressly or by any reasonable implication. Thus, to the extent the Court construes the preamble at all, it should adopt Monsanto's construction.

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[6] *See Genentech, Inc. v. Amgen, Inc.*, 289 F.3d 761, 771 (Fed. Cir. 2002) ("In the context of the patented invention, the term 'control region' describes functional control elements involved in the production of a protein and is directed to a sequence of DNA, *not a method for constructing such a sequence*.") (emphasis added); *see also Intervet*, No. 2009-1568, Slip. Op. at 13 (agreeing with plaintiff that district court's construction of DNA claim improperly included a "manufacturing requirement" that had "no place in a proper analysis" of the claim).

2. The Elements of the Recombinant DNA Molecules are Fully Defined or Described in the Specification

Defendants also misconstrue all five elements in the body of claims 103 and 131.

a. *A "promoter which functions in plant cells to cause the production of an RNA sequence"*

Claim Term	Monsanto's Construction	Defendants' Construction
A "promoter which functions in plant cells to cause the production of an RNA sequence"	"a region of DNA capable of regulating the transcription of DNA in a plant cell."	The recombinant DNA molecule "includes a sequence of bases that actually functions to signal a cellular enzyme (RNA polymerase) to associate with the DNA, and to initiate the cellular process (transcription into mRNA using one of the DNA strands as a template) of making a corresponding, complementary strand of RNA." "The particular sequence of bases works efficiently to actually cause the production of the RNA in any plant cell." (Dkt. 243 at 16)

The "promoter" is the region of the DNA molecule capable of regulating the transcription of DNA in a plant cell. Defendants, however, load the claim with additional requirements that the promoter has a sequence of bases that "*actually* functions" and "*works efficiently*" to cause the production of RNA "*in any plant cell*." (Dkt. 243 at 16). Defendants' additions are not stated in the claim, and do not make sense in the context of the claim or the patent's specification.

The patent defines the term "a promoter which functions in plant cells." It provides: "*[t]ranscription of DNA into mRNA is regulated by a region of DNA* usually referred to as the "*promoter*." (7:40-41) (emphasis added). It proceeds to define promoters that "function[] in plant cells": "Promoters which are *known or found to cause transcription of DNA in plant cells* can be used in the present invention." (70:60-61 (emphasis added)). It identifies several examples of promoters that regulate the transcription of DNA in various types of plant cells. (7:46-59, 7:62-66). This description entirely supports Monsanto's construction.

Defendant's construction goes astray in several ways. First, Defendants require the promoter "*actually* functions," and thus, they require the promoter to be in an active *process* in a

plant cell for the DNA molecule to be infringed. That is wrong.[7] The claim *can* be infringed by a plant cell containing an active promoter, but it also can be infringed by a DNA molecule outside of a plant cell, for instance, in a vector where the promoter is not actively functioning. *See Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371, 1377-78 (Fed. Cir. 2009) (holding product claim to "a frame … which temporarily deflects and subsequently rebounds to snap-secure" recited "a structural attribute possessed by the claimed frame and is not a process limitation"); *Intel Corp. v. U.S. Int'l Trade Comm'n*, 946 F.2d 821, 832 (Fed. Cir. 1991) (holding "the accused device, to be infringing, need only be capable of operating in the page mode.... [A]ctual page mode operation in the accused device is not required."); *see also R.A.C.C. Indus., Inc. v. Stun-Tech, Inc.*, 1998 WL 834329, at *3 (Fed. Cir. Dec. 2, 1998) ("This court has never determined that functional language in a claim converts an apparatus claim into a method of use or hybrid claim.").[8]

Furthermore, claims dependent on claims 103 and 131 (*e.g.*, claims 128-29, 143-44) *require* the DNA to be in a "plant" or a "plant cell," and thus make clear that the independent claims cover the DNA molecules inside ***or*** outside of the plant cell. If claims 103 and 131 were construed to require a promoter actually functioning in a plant cell, the narrower dependent claims would be redundant, in direct violation of the doctrine of claim differentiation. *See RF Delaware, Inc. v. Pacific Keystone Techs., Inc.*, 326 F.3d 1255, 1263-64 (Fed. Cir. 2003).

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[7] It also directly conflicts with Defendants' own proposed construction of the preamble, which they interpret to *exclude* the DNA molecule from being in plants. (Dkt. 243 at 9).

[8] Defendants suggest Monsanto "construed" the claim during prosecution to require the DNA actively function in plant cells. (Dkt. 243 at 30). That is wrong. In responding to an obviousness rejection, Monsanto argued there was nothing in the cited prior art that even disclosed a *utility* for the cited DNA. Thus, the prior art did not provide a motivation to use DNA toward the production of glyphosate tolerant plants, whether in a vector or otherwise. (Dkt. 244-5 at 3). Defendants cite *nothing* in that discussion that could be a "clear and unmistakable" disclaimer of DNA molecules existing outside of plant cells. *Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1329 (Fed. Cir. 2009).

Second, Defendants require that the promoter "*works efficiently*." Those words do not appear anywhere in the claims, the patent specification, or the prosecution history. Monsanto's inventors did not define their invention by this vague concept, which Defendants do not elucidate in any way in their brief. Defendants only imagine this term. Claim construction, however, is the exercise of defining words that are "actually in the claim." *MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1330-31 (Fed. Cir. 2007).

Third, Defendants argue that the claim "compels a construction that encompasses any sequence of bases that work in any type of plant cell." (Dkt. 243 at 17) (emphasis added). That is wrong. The patent does not require all of the promoters for use in the invention function in all plant cells, if that is indeed what Defendants mean to say. The claimed DNA molecule – and its promoter – can only be present ***in one plant cell at a time***. Thus, the patent is only concerned that the promoter is capable of causing transcription in the *cell in question*. It does not require the same promoter function ubiquitously in every type of plant cell. There is no need for it to.

Nothing in the patent requires *all* of the promoters work in *all* types of plant cells. The patent explains that the DNA molecules cover a class of promoters "known or found to cause transcription of DNA in plant cells" (7:60-62), and lists several examples (7:46-59, 7:62-66). Certainly, some of these promoters, such as the CaMV35S promoter, function universally in many types of plant cells – monocot and dicot alike. (Dellaporta Decl. ¶ 31). Others, such as the maize ubiquitin and rice actin promoters, were expected to function only in *certain types* of plant cells. (*Id.*). Despite this, the patent plainly identifies all of these promoters for use in the "present invention," as capable of initiating transcription in *relevant* plant cells. Thus, all of

these promoters fall within the claim language, *regardless* of whether an individual promoter is capable of initiating transcription in every plant cell.[9]

Defendants ignore all of this evidence, and instead base their construction on an out-of-context discussion of two Federal Circuit cases – *In re Vaeck* , 947 F.2d 488 (Fed. Cir. 1991) and *Monsanto Co. v. Syngenta Seeds*, 503 F.3d 1352 (Fed. Cir. 2007) – which addressed the issue of whether certain patent claims were enabled to their full scope when assessed *as a whole*. Although Defendants eagerly seek to have this Court construe the '247 patent in a way that permits them to make a similar invalidity argument in this case, neither *Vaeck* nor *Syngenta* supports the construction of the specific claim term – "promoter which functions in plant cells" – in the specific claim construction context the Court faces here.

Vaeck did not meaningfully address the claim construction of any particular terms, but simply analyzed the question of enablement under 35 U.S.C. § 112 to the claim *as a whole*. The patent claim in that case recited "[a] *chimeric gene* capable of being expressed in Cyanobacteria cells." 947 F.2d 488, 490 (Fed. Cir. 1991). It was undisputed this language required the gene itself be expressed in all cyanobacteria. That understanding was logical in the context of the *Vaeck* patent, because the claimed invention as a whole was the ability of a gene to function in cyanobacteria. (Also, dependent claims limited the expression to specific types of cyanobacteria, implying the independent claim covered all of them). The Federal Circuit proceeded to invalidate the broadest claim under § 112, but upheld dependent claims. *Id.* at 496.

[9] The doctrine of claim differentiation again supports this conclusion. Dependent claims relying on claim 103 and 131, such as claims 106-07 and 133-34 limit the scope of the claim to certain classes of promoters (plant DNA virus promoters) or certain promoters (CaMV35S and FMV 35S) – and ***not*** certain plants or plant cells. These dependent claims confirm that the "promoter" element in the independent claims is directed to a broader class of functional promoters, rather than a class of transformed plant cells.

In *Syngenta*, the claim was to a *"chimeric **plant** gene,"* which contained four different claim elements, all of which confirmed that the various elements of the claimed "plant gene" should function "in plant cells." 503 F.3d at 1360-61. Contrary to Defendants' suggestions, the Federal Circuit did not construe the words "functions in plant cells" in the context of the promoter limitation, or indeed, any specific limitation. [10] Rather, it looked to the claim language *as a whole* to determine the scope of enablement required. *Id.* at 1361 (holding that the "district court correctly construed ***claim 1*** of the '835 patent" as a whole) (emphasis added). The Federal Circuit held that the claim language, taken as a whole in the context of a claim to a transformed "chimeric *plant* gene," required enablement of both monocot and dicot transformation. *Id.*

These enablement decisions do not speak to the question of the proper construction of the term "promoter which functions in plant cells" in the context of the '247 patent. They addressed a different question – the scope of enablement required of the claim presented as a whole for compliance with 35 U.S.C § 112 – and different patents with different intrinsic records. Neither case dictates a construction of a *specific* claim element in the '247 patent requiring all promoters function in all plant cells. Because the construction of each patent is assessed on a patent-by-patent basis in accordance with the unique intrinsic evidence of the patent needing construction, *Vaeck* and *Syngenta* simply do not speak to the construction of the relevant term here.

The '247 patent states a recombinant DNA molecule, not a "chimeric *plant* gene," and not a gene construct expressed in all cyanobacteria. The invention relates to the novel DNA molecules encoding Class II EPSPS enzymes. The inventors claimed those DNA molecules in conjunction with promoters capable of functioning inside plant cells. By doing so, the inventors did not spontaneously convert their *compound claims* into claims to "pine trees" as Defendants

[10] Also contrary to Defendant's incorrect assertions (*e.g.*, Dkt. 243 at 9), the *Syngenta* court did not construe the claims to plant genes as process claims requiring the DNA to actively function in a plant cell.

would have the Court believe. (Dkt. 243 at 19). The inventors identified numerous different, representative promoters that work with the invented DNA constructs to initiate transcription in plant cells, and enabled the full genus of promoters for use with the invented DNA.

Defendants' attempt to misread the case law must fail. The promoter element of the '247 patent is expressly defined and described in the specification. The Court should adopt Monsanto's construction, which is based directly on that definition.

b. ***A "structural DNA sequence that causes the production of an RNA sequence which encodes an EPSPS enzyme having the sequence of …"***

Claim Term	**Monsanto's Construction**	**Defendants' Construction**
A "structural DNA sequence that causes the production of an RNA sequence which encodes an EPSPS enzyme having the sequence of …"	"a DNA sequence capable being transcribed that contains the genetic code for" the specified amino acid sequence	The recombinant DNA molecule also includes "a sequence of bases following the promoter that actually causes a plant cell to produce a certain RNA molecule that starts at and includes a start codon and that ends at and includes a stop codon. That RNA molecule causes a plant cell to produce an EPSPS enzyme of the defined sequence."

The next element of the claim – the "structural DNA sequence" – refers to the DNA sequence that contains the genetic code for the specified amino acid sequence (*e.g.*, SEQ ID NO:3 or NO:70), that is capable of being transcribed by the promoter. Defendants' construction, however, again imports multiple additional limitations into the claims. They require the DNA "*actually* causes" the production of an extremely precise RNA molecule that "*starts at and includes a start codon and that ends at and includes a stop codon*." (Dkt. 243 at 25). Next, they require the *RNA molecule* to cause the production of an EPSPS enzyme (*id.*), which Defendants further require to have the "*exact*" sequence specified in the claim, be "*kinetically efficient*" and have defined "*catalytic*" properties. (*Id.* at 30). Defendants' proposal should be rejected.

First, Monsanto has previously addressed the erroneous notion that the claim requires the DNA to be actively functioning in order to be infringed. The claim is to a DNA molecule, not a process, and it should be construed accordingly. *See, e.g.*, *Gemtron*, 572 F.3d at 1377-78.

Second, the claim is not limited to a particular RNA transcript that "starts at and includes a start codon and that ends at and includes a stop codon." These limitations do not appear in the claim, and as a matter of law, cannot be imported into them. The Federal Circuit has clearly stated "[i]t is improper for a court to add 'extraneous' limitations to a claim, that is, limitations added 'wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim.'" *Amgen Inc.*, 314 F.3d at 1325 (citing and quoting *Hoganas AB v. Dresser Indus., Inc.*, 9 F.3d 948, 950 (Fed. Cir. 1993)).

Defendants' limitations on the RNA transcript cannot be reconciled with the patent specification or the understanding of a person skilled in the art. The start codon consists of the bases that begin the process of *translating* a protein; the stop codon is the series of bases that ends translation. (Dellaporta Decl. ¶ 51). These codons do not define the beginning or end of the RNA *transcript*, and the patent specification contains no examples of RNA transcripts beginning at a start codon. (*Id.*). Rather, the patent expressly states that the RNA transcript can include additional bases *upstream* of the start codon at the 5′ end of the transcript that are transcribed but not translated. (*See* 8:14-15 ("The mRNA produced by a DNA construct of the present invention also contains a 5′ non-translated leader sequence.")).

Lacking anything in the '247 patent to support their construction, Defendants look to an *unrelated* 1984 PCT application, which purportedly states that a structural DNA sequence – and hence the RNA – "begins with and includes a start codon and ends with and includes a stop codon." (Dkt. 243 at 25). However, the cited PCT application says no such thing, either on the

cited page or anywhere else. (Ex. T to Dkt. 243). It simply describes the process of translation. Indeed, that application, like the '247 patent that is actually relevant here, recognizes that there are 5′ portions of the RNA transcript that are upstream of the start codon. (*Id.* at 4).

Third, Defendants are again wrong to require an RNA molecule produce a specific enzyme. The claims are to *DNA molecules*. As discussed previously, these claims do not require the production of an EPSPS enzyme, much less an enzyme with specific catalytic properties identified nowhere in the claim; they require the *DNA* to *encode* it. Defendants also ignore the fact that the specification, when describing the claim language, confirms that it is the DNA, not the RNA, that contains *the code for* the Class II EPSPS enzyme. (8:67-9:2). Indeed, the patent itself does not recite any particular RNA sequences. The inventors isolated and claimed DNA molecules, not RNA molecules, and it would be improper to construe the invented subject matter to be limited to an RNA sequence that is not reported in the patent specification.

c. ***A "3′ non-translated region that functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3′ end of the RNA sequence"***

Claim Term	Monsanto's Construction	Defendants' Construction
A "3′ non-translated region that functions in plant cells to cause the addition of a stretch of polyadenyl nucleotides to the 3′ end of the RNA sequence"	"a region of DNA capable of signaling polyadenylation in a plant cell"	"a sequence of bases following the structural DNA that actually functions to terminate transcription in any plant cell and to signal and cause the addition of a large number of A's (adenosines) to the end (3') of the RNA molecules produced by the structural DNA."

The 3′ non-translated region (or "3′ NTR"), as the claim language expressly states, is the region capable of signaling polyadenylation in a plant cell. Defendants, however, concoct requirements that the 3′ NTR "*actually* functions to *terminate transcription in any plant cell.*" Once again, their attempts to rewrite the claim must fail.

If the inventors had wanted to require the 3′ NTR to terminate transcription, they would have included such a limitation in their patent claim. They did not. The claim mentions polyadenylation, not termination, and the specification is entirely consistent with the claim. When the specification defines the 3′ NTR in the "Background of the Invention" it refers only to polyadenylation, and *does not mention* transcription termination. (7:37-39 ("This processing involves a 3′ non-translated region which adds polyadenylate nucleotides to the 3′ end of the RNA."); *accord* 8:54-56)). The one example Defendants cite from the specification merely referring to a 3′ "termination" sequence does not justify importing an additional *requirement* into the claims that the 3′ NTR must function to cause termination. *See Northern Telecom Ltd. v. Samsung Elecs. Co., Ltd.*, 215 F.3d 1281, 1290 (Fed. Cir. 2000) ("This court has repeatedly and clearly held that it will not read unstated limitations into claim language.")

Finally, contrary to Defendants' assertion, the 3′ NTR does not have to function to cause termination in "all plant cells." Like the promoters, the patent describes the 3′ NTR as the class of 3′ regions that are capable of signaling polyadenylation. (8:54-65; Dellaporta, ¶ 60). The patent does not require the 3′ NTR to signal polyadenylation in every single plant cell. Again, there is no need for it to do so. It only has to be capable of signaling *polyadenylation* in a plant cell of interest. The claim term should be construed accordingly.

d. *"where the promoter is heterologous with respect to the structural DNA sequence"*

Claim Term	Monsanto's Construction	Defendants' Construction
"where the promoter is heterologous with respect to the structural DNA sequence"	"the promoter does not come from the same gene as the structural DNA sequence"	"the sequence of bases that actually functions as the promoter is from a different source and is a different sequence than the native promoter of the structural DNA."

The requirement of the claim that the promoter be "heterologous" with respect to the structural DNA sequence means the promoter does not come from the same gene as the

structural DNA; the parties appear to agree on that much. Defendants, however, again require that the promoter "actually functions," and thus, improperly imply that the promoter must be in an active state to be infringed. As we have shown previously, the claims are to DNA molecules, not processes. The Court should thus adopt Monsanto's proposed claim construction.

e. ***"adapted to cause sufficient expression of the encoded EPSPS enzyme to enhance the glyphosate tolerance of a plant cell transformed with the DNA molecule"***

Claim Term	Monsanto's Construction	Defendants' Construction
"adapted to cause sufficient expression of the encoded EPSPS enzyme to enhance the glyphosate tolerance of a plant cell transformed with the DNA molecule"	"the promoter is capable of causing transcription of enough structural DNA to increase the glyphosate tolerance of a transformed plant cell"	"The sequence of bases that actually functions as the promoter is designed and constructed to actually cause the EPSPS enzyme, defined by the structural DNA sequence, to be produced by a plant cell in a large enough amount to make the plant cell substantially tolerant to glyphosate."

The final element of the claim requires that the promoter be capable of causing transcription of enough structural DNA to increase the glyphosate tolerance of a transformed plant cell. Defendants, however, badly misconstrue this term to require, in the same breath: an active process, an intentional design and construction, a production of a specific EPSPS enzyme with specific properties, and a plant cell "*substantially* tolerant to glyphosate." This hodgepodge of disparate concepts cannot constitute a valid construction of an element of a DNA molecule.

First, the phrase "adapted to cause" does not require that the promoter be intentionally "designed and constructed." In fact, the preferred promoters for use in the invention were *not* intentionally "designed and constructed." The inventors did not "design" all of the nucleotide sequences in the CaMV35S or the FMV 35S promoters. They did not "construct" them. They did not mean the word "adapted" to exclude these preferred embodiments. Defendants cannot avoid infringement by claiming that they did not deliberately "design" or "construct" the promoter in the DNA molecule they have misappropriated from Monsanto. They infringe

(among other reasons) by using Monsanto's DNA molecule – they did not need to design and make it or any of its component parts. There "is no intent element to direct infringement," *Intel Corp.* 946 F.2d at 832, and the claim cannot be construed to require one.

The phrase "adapted to cause sufficient expression" means that the promoter is capable of causing sufficient expression to result in an increase of glyphosate tolerance. For instance, the promoter must be "adapted" in the sense that it is in the correct orientation so that RNA polymerase transcribes in the correct direction. (Dellaporta Decl. ¶ 36). Likewise, the promoter must be in a configuration so that it is capable of initiating the transcription of the *correct strand* of DNA. (*Id.*). The claim term imposes a *structural* limitation, which makes sense because the claim is to a DNA molecule, not a method of making DNA or some other process that would implicate an element of intentional design. *See Power-One, Inc. v. Artesyn Techs., Inc.*, 599 F.3d 1343, 1349 (Fed. Cir. 2010) (holding phrase "***adapted to*** power a portion of the devices on the board," means "***capable of*** delivering power, at the appropriate intensity, to one or more loads on the circuit board.") (emphasis added).

Defendants' out-of-context case citations do not justify their construction,[11] nor does their deliberate misinterpretation of a selectively quoted passage from the '247 patent's specification. (Dkt. 243 at 21). The specification states, in its final paragraph, "it will be recognized that *this invention is one well adapted* to attain all the ends and objects hereinabove set forth together with advantages which are obvious and which are inherent to the invention." (48:50-53). The patent is not talking about a promoter, but the invention as a whole. Indeed, later in that same

[11] Defendants rely on one published and two unpublished district court opinions that ***predate*** the Federal Circuit's recent *Power One* decision, quoted above. None sets forth a *per se* rule that "adapted" requires an intentional element of design. They simply looked to the specific intrinsic record to interpret the claim. Indeed, even before *Power One*, the Federal Circuit had clearly stated, albeit in unpublished opinions, that "[t]he term ***'adapted to'*** is often used in claim drafting to indicate ***'capable of.'***" *Berg Tech. v. Foxconn Int'l, Inc.*, 1999 WL 96414, at *3 (Fed. Cir. Feb. 23, 1999) (unpublished) (emphasis added).

paragraph the patent says "it is to be understood that *all matter herein set forth or shown in the accompanying drawings is to be interpreted as illustrative and not in a limiting sense*." (48:59-62). Clearly, the inventors did not intend the word "adapted" to limit the scope of the "promoter" or any other part of the invention. Defendants' attempt to distract the Court with such arguments demonstrates only the futility of their position.

Second, the words "sufficient expression" do not require the production of a particular EPSPS enzyme with any particular amino acid sequence. These words cannot be construed in a vacuum. They are part of the phrase "*adapted to cause sufficient expression* of the encoded EPSPS enzyme to enhance the glyphosate tolerance of a plant cell transformed with the DNA molecule." This phrase, as Defendants concede, modifies the "*promoter*" element of the claimed DNA molecule. (Dkt. 243 at 20). The function of the promoter, as Defendants also recognize, is to regulate the *transcription of the DNA*. (*Id.* at 16). The promoter does not translate RNA into proteins. Thus, the claim language refers to the fact that the promoter is capable of sufficient transcription of the "*encoded* EPSPS enzyme" – the structural portion of the DNA code – to increase the glyphosate tolerance. (Dellaporta, ¶¶ 37-38). Again, the claims do not address the downstream processing or the ultimate protein sequence.

Third, Defendants misconstrue the phrase "*enhance* glyphosate tolerance" to require a plant cell "substantially tolerant" to glyphosate. (Dkt. 243 at 20). The word "enhance" has its plain meaning – to improve. It does not, by any stretch, mean "substantially tolerant."

Defendants' suggestion that the word "sufficient" somehow "limits these claims to certain preferred embodiments" is wrong. (*Id.* at 21). The Federal Circuit has repeatedly held "it is improper to read limitations from a preferred embodiment described in the specification – even if it is the only embodiment – into the claims absent a clear indication in the intrinsic record that

the patentee intended the claims to be so limited." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 913 (Fed. Cir. 2004); *Gillette Co. v. Energizer Holdings, Inc.*, 405 F.3d 1367, 1374 (Fed. Cir. 2005) (holding "'words or expressions of manifest exclusion' or 'explicit' disclaimers in the specification are necessary to disavow claim scope.").

Defendants do not even begin to explain how the innocuous word "sufficient" could be construed to limit the claims to a preferred embodiment. The claims say that the promoter is "adapted to cause *sufficient expression* of the encoded EPSPS enzyme ***to enhance*** the glyphosate tolerance of a plant cell transformed with the DNA molecule." It does not say that the promoter is "sufficient" to cause "*substantial* glyphosate tolerance." The specification uses the phrase "substantially tolerant" when referring to a preferred embodiment (8:3) – the *claim* does not.

Defendants' further misrepresentation of the patent specification does not change this. According to Defendants, the "specification also states that crop plants experience glyphosate-tolerance when they are *unharmed* by the application of glyphosate at levels that kill weeds." (Dkt. 243 at 22) (emphasis added). This is false. The patent never says that – anywhere. In the lines Defendants cite, but do not quote, the patent discusses the claims to weed control, and states that the methods allow "glyphosate containing herbicides to be applied to the crop to selectively *kill the glyphosate sensitive weeds, but not the crops*." (5:35-42). The patent never says that the glyphosate tolerant plants are unharmed. It only says they are *not killed*.

Finally, Defendants claim the phrase "a plant cell" requires "the term must be read to function in *all types of plant cells*." (Dkt. 243 at 22). It is not clear what Defendants mean by "this *term* must be read to function." To the extent they mean the claims require a promoter to actively function in all plant cells, Defendants are wrong for the reasons stated above.

II. The Claims to Transgenic Plant Cells, Plants and Seeds Cover, at a Minimum, the *Invented* Plants, Plant Cells and Seeds Described in the Specification

The parties' disputes regarding the claims to plants, plant cells, and seeds again relate to Defendants' improper attempts to import unstated limitations. Indeed, after previously attempting to convince the Court these claims were invalid for being impermissibly "broadened" during reissue, Defendants now contend that they are so *narrow* they require the plants be "*unharmed*" by glyphosate due to a *particular* EPSPS enzyme with *particular* kinetic properties. Defendants wrongly seek to exclude the invented subject matter from the scope of the claims.

A. The Claims Do Not Require Plants Be Perfectly Impervious to Glyphosate

Claim Term	Monsanto's Construction	Defendants' Construction
"glyphosate tolerant" plant or plant cell	"a plant or plant cell is less harmed by application of glyphosate than a similar, non-transgenic plant or plant cell	"Any differentiated plant [or plant cell or protoplast grown in culture in a laboratory] that is substantially unharmed when treated with the amount of glyphosate that would kill the equivalent plant [cell] without the EPSPS enzyme …."

The term "glyphosate tolerant" refers to the plants and plant cells described in the patent specification that are less harmed by glyphosate than the similar, non-transgenic plants. Defendants' construction, however, requires that the plant cells or plants be "***unharmed***" by the application of glyphosate that would "***kill***" the "equivalent plant or plant cell." (Dkt. 243 at 39-40). Defendants are simply wrong. Nothing requires such perfection.

Defendants cite the testing of transgenic tobacco plants. (*Id.* at 42 n.174, citing 35:60-65). All three of these tobacco plants showed at least some harm after glyphosate application. (*See* col. 36, Table VII). Defendants also cite testing of canola plants, and refer to Table IXB. (Dkt. 243 at 42 n.174, citing Table IXB). However, four of the transgenic canola plants described in Table IXB were harmed somewhat by application of glyphosate, while *all* of the transgenic canola plants in Table IXA were harmed *and* the control plant was *not killed*. (*See*

col. 39, Table IXA). Similar results are reported throughout the patent's examples, including in Example 3, which discusses the progenitor to Roundup Ready® soybeans. (*See* Monsanto's Opening Br., Dkt. 259, at 31-33).

The Federal Circuit has stated that "[a] construction that would not read on the preferred embodiment would rarely if ever be correct and would require highly persuasive evidentiary support." *SEB S.A. v. Montgomery Ward & Co., Inc.*, 594 F.3d 1360, 1369 (Fed. Cir. 2010) (quoting *Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1377 (Fed. Cir. 2005)). Here, limiting the claims to perfect plants would exclude most of the embodiments, and violate this clear law.

Finally, the prosecution history does not require perfect imperviousness to glyphosate. During prosecution, the applicants pointed out that the plants "exhibited less damage than the transgenic plant expressing the prior art enzymes, even though the plants of the present invention were spray[ed] at a 2-3 fold higher rate of glyphosate herbicide." (Dkt. 247-6 at 17065-66). The statement only identifies an advantage of the invention. It does not require a perfect plant, and certainly does not rise to the level of a "clear and unmistakable" disclaimer of claim scope that could limit the claim language. *See Cordis Corp. v. Boston Scientific Corp.*, 561 F.3d 1319, 1329 (Fed. Cir. 2009) (a prosecution history disclaimer must be "clear and unmistakable").

In the end, there is no basis to limit the glyphosate tolerant plants and plant cells to perfectly tolerant plants or plant cells. Thus, the Court should adopt Monsanto's construction, which is consistent with the plain language of the claims and intrinsic evidence.

B. The Claim Does Not Require the Production of a Specific Enzyme with Specific Catalytic Activity

Claim Term	Monsanto's Construction	Defendants' Construction
"glyphosate tolerant" plant or plant cell	The plant or plant cell is glyphosate tolerant "at least as a result of a functional Class II EPSPS DNA molecule inserted into the plant's genome."	The plant or plant cell is "is unharmed due to the production of a glyphosate-tolerant EPSPS enzyme which has the exact sequence of the SEQ ID NO: listed in the claim."

After moving for summary judgment based on the notion that the claimed glyphosate tolerant plants can be glyphosate tolerant for any reason (including through an unstated gene construct), Defendants turn about-face and argue that the plant must be "unharmed due to the production of a glyphosate-tolerant EPSPS enzyme which has the exact sequence of the SEQ ID NO: listed in the claim." (Dkt. 243 at 39-40). Defendants are still wrong. The patent is clear that the glyphosate tolerance is due at least to a functional *DNA molecule* inserted into the plant's genome *encoding* a Class II EPSPS enzyme.

The proper interpretation of these claims is dictated by the proper interpretation of the word "encoding." As discussed previously, "encoding" does not mean "producing" – it refers to the informational content of the DNA. Thus, claims 115 and 116 require that the glyphosate tolerance is due at least to the functional DNA sequence containing the genetic code for an EPSPS enzyme having the sequence of SEQ ID NO:70. Although an EPSPS enzyme is clearly produced by the plant, the claim is not concerned with the ultimate fate of a protein translated, modified, transported and processed in the chloroplast of a plant cell. It is concerned with defining a DNA molecule that ***encodes*** an enzyme of that amino acid sequence and an outcome of glyphosate tolerance.

In an attempt to support their argument, Defendants again misrepresent the patent. They argue that "the specification states that glyphosate-tolerant plants of 'the present invention' contain an EPSP synthase 'that maintain[s] catalytic activity while still conferring glyphosate tolerance'" and eliminating a need to over-produce the EPSPS enzyme." (Dkt. 243 at 41 (citing 5:30-35)). That is wrong. What Defendant cite but do not accurately quote clearly states that the plants and cells "are made glyphosate-tolerant *by the introduction of the above-described plant-expressible Class II EPSPS* ***DNA molecule*** *into the plant's genome*." (5:30-35).

The patent does not require an enzyme of any particular sequence or catalytic activity. Defendants' suggestion that the claims are concerned with "eliminating a need to overproduce the EPSPS enzyme" is baffling. It is clearly important to produce sufficient quantities of EPSPS enzyme. The patent simply identifies as an advantage of the invention that Class II EPSPS enzymes "reduce the amount of overproduction of the EPSPS enzyme in a transgenic plant necessary for the enzyme to maintain catalytic activity while still conferring glyphosate tolerance." (3:34-37). That does not mean it is somehow desirable – much less *part of the claim* – to have "minimal expression of the enzyme while still conferring glyphosate tolerance to the plant." (Dkt. 243. at 30).[12] *See, e.g.*, *i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 843 (Fed. Cir. 2010) (stating "not every benefit flowing from an invention is a claim limitation").

C. Defendants' Attempts to Misconstrue a Plant Cell, Plant, and Seed Should Be Rejected

Finally, Defendants ask the Court to interpret the words "plant," "plant cell," and "seed." These terms are clear on their face, and should not be further construed: a "plant" means a plant, a "plant cell" mean a plant cell, and a "seed" means a seed. Defendants, however, manage to err in interpreting even such basic words. They require the "plant" to be a "*differentiated* plant," the plant cell to be "[a]ny plant cell *or protoplast grown in culture in a laboratory*," and a seed to be "a structure *formed by the maturation of the ovule of the glyphosate-tolerant plant following fertilization of that plant*." (Dkt. 243 at 40). These constructions should be wholly rejected.

[12] Nor does the claim say anything about the "kinetics" of the enzyme. The Court should reject Defendants' importation extraneous limitations in the guise of interpreting the claim fragment "EPSPS enzyme." The words "EPSPS enzyme" are simply a part of the broader term "a DNA sequence encoding an EPSPS enzyme having the sequence of SEQ ID NO: 70." (*See, e.g.*, claim 115). Further, the patent's discussion of the "present invention" relating to enzyme kinetics, which Defendants attempt to import, concerns a ***different*** set of patent claims that were rejected by the Examiner during prosecution, and did not issue in the '247 patent. (*See* claims 86-87, bracketed as cancelled). Such elements cannot be resurrected by importing them into claims in which kinetic criteria were never stated.

Defendants importation of the extraneous word "differentiated" to modify the word "plant" is improper. In *Amgen*, the defendant attempted to import a modifier into the claim, requiring DNA to be "exogenous." The court rejected that construction, even though the specification stated that the invention was "uniquely characterized by the expression of exogenous DNA sequences." 314 F.3d at 1326. The court held: "The plain meaning of the claims controls here, and they plainly are not so limited." *Id.* That is also true here.

The same principle also holds true for Defendant's attempts to impose limitations on the words "plant cell." Nothing in the words "plant cell" limits the claim to a cell grown in culture in a laboratory. The claims extend to plant cells in a Petri dish or in a plant. And, contrary to Defendants' misstatements, Monsanto did not "argue[] to the PTO that claims directed to plant cells do not extend to regenerated plants." (Dkt. 243 at 39). The applicants told the Examiner she erred in rejecting claims based on the misapprehension they extended to "*all* plant species"; claims then pending were directed to plant cells and types of plants. (Dkt. 247-6 at 14).

Finally, a seed does not mean "a structure *formed by the maturation of the ovule of the glyphosate-tolerant plant following fertilization of that plant*." (Dkt. 243 at 40). A seed is patentable as a composition of matter; it should not be construed as a product produced by a process. The claims do not require Monsanto to prove the maturation of an ovule following fertilization in order to demonstrate infringement. That type of limitation would impermissibly import a process element into a clear product claim, and exclude asexually produced seeds.

III. The Claims to Methods of Weed Control Cover, at a Minimum, the Use of the *Invented* Plants, Plant Cells and Seeds Described in the Specification.

Defendants likewise misinterpret the weed-control claims in an attempt to manufacture non-existent defenses to their infringement. These claims do not require perfection, and they must be interpreted to cover the use of the plants that are actually described in the patent.

A. The Preamble is Not a Claim Limitation.

Defendants seek to construe the claim preamble as a vehicle to import additional, unstated limitations into the claim. The preamble recites "a method for selectively controlling weeds in a field containing a crop having planted crop seeds or plants comprising the steps of ..." It merely gives context, and is "reasonably susceptible to being construed to be merely duplicative of the limitations in the body of the claim." *Symantec Corp.*, 522 F.3d at 1288.

The claim body recites two steps: (1) "planting the crop seeds or plants which are glyphosate tolerant as a result of a recombinant double-stranded DNA molecule being inserted into the crop seed or plant…" and (2) "applying to the crop and weeds in the field a sufficient amount of glyphosate herbicide to control the weeds without significantly affecting the crop." These two elements fully define the claim. The preamble, which recites a method "for selectively controlling weeds" simply echoes the claim body.

Contrary to Defendants' assertions, the preamble does not require "plants that are expected to *produce a desirable harvest*." It only says "crops," which are described later in the claim as the "crop *seeds or plants* which are glyphosate tolerant as a result of a recombinant double-stranded DNA molecule being inserted into the crop seed or plant." Further, the preamble imparts no requirement that the infringer *intend* to "produce a desirable harvest," as Defendants suggest. *Intel Corp.*, 946 F.2d at 832 (stating there "is no intent element to direct infringement"). The infringer only needs to perform the two steps of the method that are recited in the claim, which Defendants unquestionably do.

B. The Plants are Glyphosate Tolerant At Least Due to the Stated Functional DNA.

Second, Defendants argue that the plants are "glyphosate tolerant" due to the EPSPS enzyme encoded by the recited gene construct, which they define elsewhere to require specific

kinetic properties and an exact sequence. (Dkt. 243 at 30, 43). Their construction fails for the same reasons as stated previously. The claims specify the plants are "glyphosate-tolerant as a result of a recombinant double-stranded *DNA molecule* being inserted into the crop seed or plant," and does the specification. (*See* 5:35-40 (stating "a method for selectively controlling weeds in a crop field is presented by planting crop seeds or crop plants *transformed with a plant-expressible Class II EPSPS* ***DNA molecule*** *to confer glyphosate tolerance* to the plants.")).

C. The Method Claims Do Not Require Perfection.

Claim Term	Monsanto's Construction	Defendants' Construction
a sufficient amount of glyphosate herbicide to control the weeds without significantly affecting the crop	"any amount of glyphosate herbicide that controls the growth of unwanted plants in a field, while not causing significant harm to the planted crop or crop seeds"	"Applying enough glyphosate herbicide to kill all plants growing in the field (before they drop seeds) except those plants transformed with the recited DNA molecule, which are left unharmed, particularly the commercial properties important for harvesting."

Although Defendants recognize that "the concept of 'controlling weeds' is a term of degree" (Dkt. 243 at 43), they nevertheless construe the term as an absolute requirement that *all* weeds in the field are killed – *before they drop seeds* – except the relevant transgenic plants, which are left *unharmed* "*(particularly the commercial properties important for harvesting*)." However, the claims, by their terms, only require enough glyphosate be applied to *control* the weeds without *significantly* affecting the crop. The plain meaning governs.

Defendants cite nothing to limit "control" to absolute eradication. Their lone purported support merely states that the method allows one to "selectively kill the glyphosate sensitive weeds, but not the crops." (*Id.*). It does *not* say *all* weeds to be killed, and it says nothing about requiring the weeds be eradicated "*before they drop seeds*." The patent speaks in relative terms about the benefits of weed control, explaining that "[h]erbicide tolerant plants may *reduce the need* for tillage to *control* weeds thereby effectively *reducing* soil erosion." (1:22-26). The claim

does not impose a requirement of proving that every single one of the weeds in Defendants' fields be killed. *See CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1339-40 (Fed. Cir. 2003) (holding claim term "cleaning" meant "removal of contaminants," and "not removal of all contaminants" or removal of contaminants according to a commercial standard).

Likewise, nothing in the patent requires the plants be perfectly unharmed. And, neither the specification nor the claim say *anything* about "the commercial properties important for harvesting" that Defendants insert into their construction. On the contrary, as discussed above and in Monsanto's opening brief, the examples of glyphosate tolerant plants were *not* perfectly unharmed when applied with glyphosate that killed non-transgenic plants. The invention is the use of *the plants in these Examples*, and the claim cannot be read to exclude them. *See SEB*, 594 F.3d at 1369 (stating that exclusion of preferred embodiments is wrong as a matter of law). Defendants' attempt to interpret the claim out of existence should be rejected.

IV. Other Claim Terms, Sequence Listings, and Miscellaneous Phrases Defendants Propose for Construction

Finally, Defendants misconstrue miscellaneous terms appearing in the claims, along with various transitional phrases, and SEQ ID NOs.

A. Terms in Dependent Claims Reciting Recombinant Molecules.

1. An "[amino terminal] chloroplast transit peptide"

Claim Term	Monsanto's Construction	Defendants' Construction
An "[amino terminal] chloroplast transit peptide"	"an amino acid sequence capable of targeting an EPSPS enzyme to a chloroplast of a plant cell."	"A sequence of amino acid residues found naturally at the amine end of plant proteins that causes that protein to be imported into the chloroplast of the cell and then is removed from the protein."

The chloroplast transit peptide ("CTP") is a protein that targets the EPSPS protein to the chloroplasts of the plant cells, where the EPSPS proteins are most useful. Defendants erroneously propose that the term be construed as an active process, requiring that the CTP

"*causes*" the importation of an EPSPS protein into the chloroplast, "*and then is removed from the protein*." Claim 104, in which this claim appears, depends on claim 103, and recites a *DNA molecule* that encodes a CTP. Like the claim from which it depends, claim 104 does not require an active process; only that the DNA encode a CTP. The precise location of a CTP cleavage site is ill defined. (Dellaporta Decl. at ¶¶ 67-68). The claim is not defined according to particular location of cleavage for the CTP after processing, but rather, what the DNA encodes.

2. A "plant DNA virus promoter"

Claim Term	Monsanto's Construction	Defendants' Construction
A "plant DNA virus promoter"	"a region of DNA from a plant virus that is capable of regulating the transcription of DNA in a plant cell."	"The sequence of bases that actually function as the promoter is the same sequence as a promoter sequence in a virus that infects plant cells causing transcription of the viral genes in these plant cells." (Dkt. 243 at 22)

The term "plant DNA virus promoter" means that the promoter is from a plant DNA virus (such as the cauliflower mosaic virus that provides the promoter used in Roundup Ready). In an apparent effort to create another non-infringement defense, Defendants require the DNA virus promoter to be exactly the "same sequence" as the native promoter sequence. Nothing, however, suggests such a narrow interpretation.

Defendants attempt to ascribe significance to the fact certain claims say a promoter "is from" a plant DNA virus, while the asserted claims say a promoter "is" a plant DNA virus. Defendants overinterpret very minor differences in claim language. Contrary to Defendants' assertions, the doctrine of claim differentiation does not aid them; nothing would be rendered duplicative if "is from" and "is" are interpreted interchangeably. In fact, it would be anomalous to interpret such similar claim language so dramatically differently. There is no reason to believe

that the inventors deliberately intended to restrict the claim to the exact sequences of a native DNA virus promoter.[13]

3. A "CaMV35S promoter" or "FMV35S promoter"

Claim Term	Monsanto's Construction	Defendants' Construction
"the promoter is a CaMV35S promoter or an FMV35S promoter"	A region of DNA derived from the cauliflower mosaic virus 35S gene or the figwort mosaic virus 35S gene capable of regulating the transcription of DNA in a plant cell.	"the sequence of bases that actually functions as the promoter that consists of either: the sequence of at least the nucleotides between -343 to +9 of the cauliflower mosaic virus genome described by Odell *et al.*, 1985; or the sequence located between nucleotides 6368 and 6930 of the figwort mosaic virus genome as described in Fig. 1 (SEQ ID NO: 1) of the '247 RE patent"

Defendants also propose to dramatically limit the scope of this claim term to a 352 base pair CaMV sequence, and a single sequence of the FMV promoter reported in the specification. That is wrong. Monsanto's inventors claimed the use of *a* cauliflower mosaic virus 35S promoter or *an* FMV35S promoter – making clear that they were claiming a promoter from a CaMV35S or an FMV35 promoter, as opposed to exact sequences. Nothing in the claim requires sequence *identity* with the native promoters.

In *Monsanto Co. v. Scruggs*, 459 F.3d 1328 (Fed. Cir. 2006), the Federal Circuit addressed the meaning and validity of claims directed to a CaMV35S promoter. The court held the claims were *not* limited to a particular strain of CaMV (and thus, not limited to a particular sequence). *Id.* at 1335. Moreover, it specifically held that Roundup Ready® soybeans contain a CaMV35S promoter. *Id.* ("Scruggs' argument that the promoter in Roundup Ready® seeds is shorter than the promoter covered by the '605 patent fails because the deletions in the Roundup Ready® DNA are in the enhancer region of the DNA inserted into the cotton and soybean DNA,

[13] Typically, the native sequences of a promoter will be modified slightly during the process of incorporating them into gene constructs, for example, to allow for the ease of cloning. (Dellaporta Decl. ¶¶ 41,45). A person of ordinary skill in the art would not believe the inventors intended to exclude minor variations on the DNA sequences created during genetic engineering.

not in the promoter region. Accordingly, the Roundup Ready® seeds are covered by the '605 patent.")

Ignoring this, Defendants seek to obtain a claim construction that excludes Roundup Ready® from the claim. Defendants posit that the CaMV35S promoter must be defined by a 352 base pair ("bp") sequence defined in an Odell publication. Defendants are wrong. Odell clearly shows that a DNA sequence ***163 bp upstream*** (-163) from the start of transcription fully functions as the 35S promoter, and states this 163 bp region shows ***"no significant decrease in activity"*** compared to the 343 bp region (246-1 at 811; Dellaporta Decl. ¶¶ 43-45). As defined by Odell, all sequences required for the transcription of the 35S gene are contained within the 163 bp region. (Dellaporta Decl. ¶¶ 44). Thus, to the extent a CaMV 35S promoter should be defined according to a particular sequence of bases in Odell (it should not be), the promoter includes the 163 bp promoter region, but not necessarily the 352 bp region Defendants require.

4. A "NOS 3' or E9 3' non-translated region

Claim Term	Monsanto's Construction	Defendants' Construction
"a NOS 3′ or an E9 3″ non-translated region"	"A region of DNA derived from the 3′ nontranslated region of Agrobacterium's nopaline synthase gene or the 3′ nontranslated region of the ssRUBISCO gene from pea, capable of signaling polyadenylation in a plant cell.	"the sequence of bases that actually functions as a 3' NTR that includes either the sequence of bases extending from base 1297 to base 1554 of the nopaline synthase sequence as described in the article by Depicker *et al.* or the sequence of bases extending from base 742 to base 891 of the pea rcbS gene as described by Coruzzi *et al.*"

Dependent claims, including claim 108, recite a NOS 3′ or an E9 3′ non-translated region. (Roundup Ready® contains a NOS 3′ NTR). Contrary to Defendants' suggestions, nothing in the claim requires sequence *identity* with the native promoters. The claim simply reflects sources of the 3′ NTR, and should be given effect according to its clear language.

Defendants misconstrue this claim element to require a particular series of bases far beyond what is needed for the NOS 3′ NTR to function as claimed. They suggest, through their

expert Dr. Jacobsen, that the patent defines the NOS 3′ NTR according to a 1982 Depicker article to include the 257 bp from base 1297 to base 1554 of the NOS sequence. That is scientifically and legally wrong. As Dr. Dellaporta explains, Depicker does not define the NOS 3′ NTR according to those sequences. (Dellaporta Decl. ¶¶ 63-64). And, in any event, the plain language of the patent claim does not require a sequence identical to a natural sequence.

B. Transitional Phrases and *Markush* groups

Defendants also misconstrue "having the sequence of," "has the sequence of," "has the sequence set forth in" and "selected from the group consisting of" to require exactitude.

1. The term "having" or "has" does not limit the claim to an "exact" sequence.

An inventor can use either open-ended transitional phrases or closed-ended phrases to defined the claimed invention. The term "comprising," for example, is " well understood in patent law to mean 'including but not limited to,'" *Exergen Corp. v. Wal-Mart Stores, Inc*., 575 F.3d 1312, 1319 (Fed. Cir. 2009), and is to be distinguished from the terms such as "consisting essentially of" and "consisting of," which generally restrict the claim from including other elements. *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360-61 (Fed. Cir. 2007).

The Federal Circuit has generally interpreted "having" to be an open-ended phrase synonymous with "comprising." In *CIAS, Inc.*, the Federal Circuit noted "[o]ther words, less often used, have been given the same meaning in patent claim interpretation as '***comprising***': 'including,' '***having***,' 'containing,' and even 'wherein.'" 504 F.3d at 1361 (citing "Robert A. Faber, Landis on Mechanics of Patent Claim Drafting § 2:5, 2-15 (5th ed. 2006) (emphasis added). Other Federal Circuit cases have reached similar conclusions. *See Crystal Semiconductor Corp. v. TriTech Microelectronics Int'l, Inc*., 246 F.3d 1336, 1348 (Fed. Cir. 2001) ("The transition 'having' can also make a claim open."); *Regents of the Univ. of Cal. v. Eli*

Lilly & Co., 119 F.3d 1559, 1573 (Fed. Cir. 1997) (stating that an amendment to a claim during prosecution adding the term "having" "still permitted inclusion of other moieties").[14]

Defendants ignore all of this case law, and contend that a clerical amendment to the claims during prosecution somehow caused a change in the meaning of "having" to make it closed-ended. That is nonsense. During the reissue prosecution, Monsanto modified the phraseology of application claim 107 (claim 103 of the '247 patent) as follows:

> A recombinant, double-stranded DNA molecule comprising in sequence: . . . b) a structural DNA sequence that causes the production of an RNA sequence [that comprises the sequence encoding] which encodes an EPSPS enzyme [comprising] having the sequence of SEQ ID NO:70.

(Dkt. 247-5 at 24). Monsanto explained the claim was amended to "*parallel the language of the claims originally issued in United States Patent No. 5,633,435*," and thus to preserve consistency across the patent. (*Id.* at 33). It was *not* made to limit the claim over prior art.

This amendment – which only applied to asserted claim 103 – does not limit the word "having" to mean "exactly" the sequence set forth.[15] The claim recites a recombinant DNA molecule "*comprising* in sequence" a structural DNA sequence "which encodes an EPSPS enzyme *having* the sequence of SEQ ID NO:70." Both the open-ended term "comprising" and the similarly open-ended term "having" permit additional nucleotides in the claimed DNA molecule. In *Eli Lilly*, the Court addressed a similar situation, and noted that a claim amendment

[14] The single unpublished Federal Circuit case Defendants cite is not to the contrary. In that case, the court addressed the meaning of "having" in a claim to a *range* of nucleotides from "about 4 to about 12 nucleotide triplets." *Pieczenik v. Dyax Corp.*, 76 Fed. Appx. 293, at *2 (Fed. Cir. Sept. 23, 2003) (unpublished). Obviously, interpreting the claim as open-ended eviscerated the range. That case has no relevance here, where the claims contain no range limitations that would be eviscerated by an open-ended construction.

[15] Other claims, such as claim 1, always recited a DNA molecule encoding an enzyme "having" a certain sequence. These open-ended claims would not be impacted by Defendants' argument, even assuming it had merit, which it does not.

adding the word "having" – made in an *attempt to distinguish prior art*, unlike here – nevertheless did *not* exclude additional DNA sequences. 119 F.3d at 1573.

In this case, limiting the word "having" would irrationally exclude the claim from covering other elements, such as a chloroplast transit peptide, that the inventors plainly contemplated would be covered by the invention. (4:16-23). Indeed, dependent claim 104, relying on claim 103, *recites* a chloroplast transit peptide, and shows that claim 103 *cannot* be closed-ended in the way Defendants propose.

Defendants also wrongly assert that construing "having" in an open-ended manner "would eviscerate the very purpose of setting forth precise requirements." (Dkt. 243 at 36). The stated sequences are not eviscerated by interpreting the claims as open-ended, according to their express terms. The MPEP section Defendants purport to rely on says nothing about the meaning of "having," nor does it restrict the interpretation of claims. (*Id.* at 36-37). Rather, the end of that section specifically states that it "do[es] not in any way restrict the manner in which an invention can be claimed." MPEP § 2422.03.

2. The *Markush* term "selected from the group consisting of" does not require an "exact" sequence.

Defendants are equally wrong to suggest that the term "selected from the group consisting of," which appears in certain asserted claims, imparts an "exact" sequence requirement on the claims. This type of language merely indicates that the claim element in question is drawn to one of the specified alternatives. It does require the claim *as a whole* be of the "exact" sequence of one of the recited alternatives. Thus, two days ago, the Federal Circuit held a claim to a DNA molecule stating "a sequence selected from the group consisting of" did not exclude "a broader claim construction that allows for some variation in the precise limits." *See Intervet Inc. v. Merial Ltd.*, No. 2009-1568, Slip. Op. at 5-6, 12 (Fed. Cir. 2010). Likewise,

in *In re Crish*, the Federal Circuit held that the addition of closed language ("consists") to a single *element* of a DNA claim "*comprising*" certain elements did "not preclude a DNA sequence having additional nucleotides." 393 F.3d 1253, 1257 (Fed. Cir. 2004); *see also Mannesmann Demag Corp. v. Engineered Metal Prods. Co., Inc*., 793 F.2d 1279, 1283 (Fed. Cir. 1986). Thus, this phraseology itself does not require exactitude. Moreover, all of the claim elements using this phraseology are part of (or dependent on) larger claims to DNA molecules that are drafted in open-ended fashion.[16] The claims as a whole should not be limited to exclude additional elements, such as a 5′ leader sequence, which the inventors recognized as part of the invented gene constructs. (8:14-27).

C. SEQ ID NOs

Finally, in their brief and "Appendix A," Defendants propose constructions for each SEQ ID NO identified in the asserted claims, for which they give qualitative descriptions, but nevertheless require to have "exact" sequences. Defendants' descriptions of the SEQ ID NOs must be rejected. Contrary to Defendants' assertions, the claims do not say "exact," nor does the mere recitation of sequences imply exactitude.

Indeed, days ago, the Federal Circuit reversed such a narrow construction of a DNA claim. *Intervet*, No. 2009-1568, Slip. Op. at 11. It held the district court "erred in confining the scope of the term ["ORFs 1-13"] to the precise limits of the representative ORFs listed in Example 13, and the exact DNA sequence of SEQ ID 4." *Id.* The court held such a construction was "improperly narrow" given that the specification identified "some variation" and that "one of skill in the art would understand that slight natural variation is to be expected." *Id.* The court

[16] Contrary to Defendants' assertions, claim 131 is not a "Markush" claim reciting "selected from the group consisting of." Rather, the structural DNA sequences in this claim are introduced with the transition "having," and should be construed like the other terms reciting "having," discussed above.

also noted that strictly limiting the claim to the "exact sequences" would improperly exclude embodiments described in the specification. *Id.* "Thus a broader claim construction that allows for some variation in the precise limits of the ORFs and of the underlying DNA sequence is consistent with the expectations of a skilled artisan reading the patent disclosure." *Id.* at 12.

Here too, the sequence listings would be understood by a skilled artisan to allow for at least slight variations in DNA or amino acid sequences caused by cloning or peptide fusion. The '247 patent specifically contemplates such variations, and describes how the DNA sequences were slightly altered during the process of creating a restriction site that allowed for the fusion of DNA encoding a chloroplast transit peptide (resulting in a very slight change of amino acid sequence). (29:13-24, 29:56-62; *see* Dellaporta, ¶¶ 74-77). Construing the sequences to allow for such trivial variations is "consistent with the expectations of a skilled artisan reading the patent disclosure." *Intervet*, No. 2009-1568, Slip. Op. at 12. (Dellaporta, ¶¶ 73-78). That is particularly true because *each* of the vectors constructed from SEQ ID NO:3 involved such minor variations for convenience of cloning (Dellaporta, ¶ 78). An "exact" construction would impermissibly exclude these embodiments from the literal scope of SEQ ID NO:3. *See Intervet*, No. 2009-1568, Slip. Op. at 11 (holding construction was "improperly narrow" where it excluded such embodiments). Thus, the SEQ ID NOs should be construed to embrace the recited nucleotide and amino acid sequences, including slight variations resulting from cloning.

CONCLUSION

The Court should adopt Monsanto's proposed constructions.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 6th day of August, 2010, the foregoing was filed electronically to the Clerk of Court for the United States District Court Eastern District of Missouri, Eastern Division and served by ECF notice by operation of the Court's electronic filing system upon the following:

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

MONSANTO COMPANY and MONSANTO TECHNOLOGY LLC,	)	
Plaintiffs,	)	
vs.	)	
E.I. DUPONT DE NEMOURS AND COMPANY and PIONEER HI-BRED INTERNATIONAL, INC.,	)	Case No. 4:09-cv-686 ERW
Defendants.	)	

MONSANTO'S RESPONSE TO DEFENDANTS' CLAIM CONSTRUCTION BRIEF

EXHIBIT 1

United States Court of Appeals for the Federal Circuit

INTERVET INC.,
Plaintiff-Appellee,

v.

MERIAL LIMITED AND MERIAL SAS,
Defendants-Appellants.

2009-1568

Appeal from the United States District Court for the District of Columbia in case no. 06-CV-0658, Judge Henry H. Kennedy, Jr.

Decided: August 4, 2010

WILLIAM G. JAMES, II, Kenyon & Kenyon LLP, of Washington, DC, argued for plaintiff-appellee. With him on the brief were JOHN R. HUTCHINS and YARIV WAKS; RICHARD L. DELUCIA and MICHAEL D. LOUGHNANE, of New York, New York. Of counsel was PATRICE P. JEAN, of New York, New York.

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MELTON, Alston & Bird LLP, of Atlanta, Georgia; MADISON C. JELLINS, of Palo Alto, California. Of counsel on the brief were JUDY JARECKI-BLACK, Merial Limited, of Duluth, Georgia; EDGAR H. HAUG, and THOMAS J. KOWALSKI, Frommer Lawrence & Haug LLP, of New York, New York.

Before BRYSON, DYK, and PROST, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* PROST.

Opinion concurring-in-part, dissenting-in-part filed by *Circuit Judge* DYK.

PROST, *Circuit Judge*.

The present patent infringement case arises from a declaratory judgment action brought in the United States District Court for the District of Columbia on April 11, 2006. Plaintiff Intervet Inc. ("Intervet") denies infringing U.S. Patent No. 6,368,601 ("'601 patent"), owned by Defendants Merial Limited and Merial SAS (collectively "Merial"), directed to DNA constructs encoding a type of porcine circovirus. The district court entered summary judgment of noninfringement based on its construction of six disputed claim terms. Merial appeals the district court's claim construction for three of the terms, and, in the alternative, appeals the district court's summary judgment of noninfringement based on the doctrine of equivalents.

Because we agree with Merial that the district court erred in its construction of two disputed claim terms, we reverse the district court's claim construction, vacate the judgment of noninfringement, and remand for a finding of whether the accused device infringes under the claim

construction articulated herein. Additionally, because we agree with Merial that the district court misapplied the law of prosecution history estoppel, we instruct the district court to consider on remand arguments related to literal infringement and to infringement under the doctrine of equivalents, consistent with the analysis herein.

BACKGROUND

Postweaning Multisystemic Wasting Syndrome ("PMWS") is a disease affecting livestock pigs. Researchers at Merial learned that PMWS is associated with a particular type of porcine circovirus.[1] The scientific community was aware of porcine circoviruses prior to Merial's findings. Known porcine circoviruses, however, were not observed to be pathogenic, meaning they did not appear to cause disease in infected pigs. Merial filed for the '601 patent pertaining to the discovery of what it described as a previously unknown pathogenic type of porcine circovirus that the inventors dubbed "PCV-2." PCV-2 stands for "porcine circovirus type II." Merial's patent categorizes previously known, nonpathogenic porcine circoviruses as belonging to "type I" or "PCV-1". The patent identifies a particular known DNA sequence isolated from pig kidney cells called PK/15 as being representative of type I. The '601 patent then identifies five isolated pathogenic porcine circovirus strains as being representative of type II.

The patentee placed the five representative strains on deposit with the United States Patent and Trademark Office ("PTO") as part of the description of the invention. The written patent disclosure provides the full DNA

[1] The prefix "circo" refers to the circular genome of the virus. A porcine circovirus is thus a virus having a circular genome that infects pigs.

sequence for four of these strains, as well as the full sequence of PK/15.

The disclosure explains that the deposited PCV-2 strains had been detected in lesions of pigs with PMWS, but not in healthy pigs. The patent description observes that the sequenced strains exhibit 96% nucleotide homology with each other, and only 76% nucleotide homology with PK/15.[2] The description concludes from these observations that there are two types of porcine circoviruses, and that nonpathogenic "type I," as represented by PK/15, is "thus" distinct from pathogenic "type II," as represented by the five isolated strains. '601 patent col.1 ll.48-62. The disclosure then identifies the subject of the present invention as "the group II porcine circovirus, as defined above, isolated or in the form of purified preparation." *Id.* at col.1 ll.63-65.

The patent disclosure goes on to analyze the sequenced PCV-2 strains in more detail, providing tables comparing the sizes and alignments of the strains. The disclosure then identifies one of the sequenced strains, designated SEQ ID 4, as being further representative of the other strains, and identifies thirteen open reading frames ("ORFs") for PCV-2 using that sequence. The '601 specification identified nine of the thirteen disclosed ORFs that are unique to PCV-2, and four that are present in both PCV-2 and PCV-1.

"ORF" is a commonly used term in molecular genetics that has a standard textbook meaning. An ORF is a portion of a gene that contains a sequence of nucleotide

[2] "Homology" is a measure of the similarity of sequences. Sequences with 96% nucleotide homology, for instance, are 96% identical at the nucleotide level.

bases that may be translated into a protein. Each amino acid of a protein is encoded by a DNA codon. A codon consists of three adjacent nucleotide bases. The first codon in an open reading frame is the "start" codon, which encodes a modified form of methionine. Each amino acid in the polypeptide chain is encoded by a subsequent set of three base pairs, until the translation is terminated at a stop codon that does not itself encode an amino acid, but rather signals the end of translation. Thus, a double-stranded length of DNA can have six different reading frames, depending on the starting base-pair of the first codon and the direction in which the strand is read.[3] The length of an ORF is thus defined by the number of codons that lie between a start codon and a stop codon within the same frame.

Identifying the ORFs of a gene sequence differentiates the portions of the sequence that may encode a protein from the portions that do not encode a protein. It allows those skilled in the art to estimate the size and composition of potential amino acid sequences for the proteins encoded by the gene. Identifying ORFs is especially important in the context of viral or prokaryotic DNA, which can contain several overlapping ORFs in the same gene sequence.

There are two groups of claims in the '601 patent relevant to the present case. The first group can be represented by independent claim 9, which reads:

> 9. A vector comprising an isolated DNA molecule comprising a sequence selected from the group

[3] Two strands times three base pairs per codon equals six reading frames.

> consisting of ORFs 1 to 13 of porcine circovirus type II.

The second group can be represented by independent claim 32, which reads:

> 32. An isolated DNA molecule comprising a nucleotide sequence encoding an epitope which is specific to PCV-2 and not specific to PCV-1.

An epitope is an immunodominant region of a protein, meaning it is the part of an antigen peptide that is recognized by antibodies of the immune system. The patent explains that certain epitopes found among strains of PCV-2 are not present in PCV-1. Thus, the regions of DNA encoding these epitopes are unique to PCV-2. Epitopes unique to PCV-2 are relevant to diagnostics or treatments, because antibodies specific to these epitopes will recognize and bind to the pathogenic PCV-2, but will ignore the benign PCV-1.

Merial's patent claims cover certain vectors and other DNA molecules that contain portions of the PCV-2 gene sequence. These molecules are believed to be useful in diagnosing and vaccinating against PMWS, by stimulating the production and activity of antibodies against PCV-2.

Intervet is an animal healthcare company that manufactures vaccines for livestock. Intervet developed a vaccine called "Porcine Circovirus Vaccine Type 2" that contains a porcine circovirus nucleotide sequence in a vector for treating PMWS in pigs. Merial alleges that Intervet's PMWS vaccine uses an infringing PCV-2 sequence.

At a *Markman* hearing, the United States District Court for the District of Columbia construed six disputed claim terms of the '601 patent. Among these constructions, the district court defined the term "porcine circovirus type II" as consisting of the five nucleotide sequences that Merial placed on deposit with the PTO. The district court construed the term "ORFs 1-13" as the DNA sequences of the thirteen ORFs of SEQ ID 4 listed in the table under Example 13 of the patent. Finally, the district court construed claim 32 in its entirety to refer (in part) to a construct comprising at least one DNA molecule that is unique to one of the five sequences on deposit with the PTO.

The district court then entered summary judgment of noninfringement based on these claim constructions. It was undisputed that Intervet's vaccine contained a nucleotide sequence that was 99.7% homologous to one of the deposited sequences. The accused product was therefore held to be outside the literal claim scope of PCV-2, which required strict identity to one of the five deposited sequences. The district court also held that the doctrine of prosecution history estoppel precluded Merial from arguing that the accused sequence infringed under the doctrine of equivalents.

Merial timely appealed to this court, arguing that the district court erred in its claim construction and erred in applying the doctrine of prosecution history estoppel to Merial's equivalence arguments for the accused product. For the reasons discussed below, we agree with Merial that the district court erred in its claim construction and application of prosecution history estoppel.[4]

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[4] We do not address the issues of validity and non-patentable subject matter discussed by the dissent

DISCUSSION

Claim Construction

Claim construction is a question of law that is reviewed de novo. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (Fed. Cir. 1995) (en banc). To the extent possible, claim terms are given their ordinary and customary meaning, as they would be understood by one of ordinary skill in the art in question at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc). Idiosyncratic language, highly technical terms, or terms coined by the inventor are best understood by reference to the specification. *Id.* at 1315. Such understanding is informed, as needed, by the prosecution history, if it is in evidence. *Id.* Construing the claims in light of the specification does not, however, imply that limitations discussed in the specification may be read into the claims. It is therefore important not to confuse exemplars or preferred embodiments in the specification that serve to teach and enable the invention with limitations that define the outer boundaries of claim scope. *Id.* at 1323.

It is with an eye to these tenets of claim construction that we review the district court's *Markman* order and conclude the district court erred. We discuss each term in turn.

"Porcine Circovirus Type II"

The district court found that the claim term "porcine circovirus type II" was limited to the five sequences that

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because these issues were not addressed by the district court or raised on appeal.

were deposited with the PTO as part of the description of the invention. The district court was persuaded by Intervet's arguments that the patent specification defined the invention as being these five sequences, and contained no disclosure from which to infer that any other sequences were also part of the invention.

It is clear enough to us, however, that the patent states that the five deposited strains and listed sequences are "*representative* of" a "*type* of porcine circovirus," and thus do not constitute the entire scope of the invention. '601 patent col.1 ll.60-61 (emphases added). Sequences are representative of the scope of broader genus claims if they indicate that the patentee has invented species sufficient to constitute the genera. *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 967 (Fed. Cir. 2002); *In re Smythe*, 480 F.2d 1376, 1383 (C.C.P.A. 1973). Here, the deposited strains are representative species of the larger "type II" genus, where the genus is identified and claimed as the invention.

Claims properly directed to a genus may be adequately supported by the patent disclosure if a sufficient number of species is disclosed so as to properly identify the scope of the genus. *Id.* Here, the patentee has disclosed five species of PCV-2, provided the full sequences for four, and identified the potential coding portions of the sequences. The patentee also provided a counterexample, PCV-1, that by definition lies outside the scope of the claimed genus, as well as a representative species of the counterexample, its sequence, and potential coding portions for the representative.

Neither the claim itself nor the specification provides a homology threshold above or below which a particular PCV strain is properly considered PCV-2 rather than

PCV-1. It refers instead to strains of the invention having "significant serological similarity" and stringent, selective cross-hybridization to the deposited strains over PK/15. The only quantitative boundaries disclosed in the patent are the 96% homology among representative PCV-2 sequences, and the 76% homology between those sequences and the representative of PCV-1.

The patent's stated conclusion that the disclosed PCV-2 sequences "thus" represent a new type of porcine circovirus is based on the pathogenicity of the isolated strains, as well as the observed homology patterns. *See, e.g.*, '601 patent col.5 ll.59-61. This conclusion comports with the way that viruses are typically classified in the relevant art. *Cf.* Universal Virus Database of the International Committee on Taxonomy of Viruses *available at* http://www.ictvdb.rothamsted.ac.uk/. The invention is then defined as being the type II porcine circovirus, which is in turn "as defined above." '601 patent col.5 ll.64. Thus, the pathogenicity and homology patterns are the defining properties of the new type of virus. The claim construction of "porcine circovirus type II" is therefore properly limited to porcine circoviruses that have these two defining properties.

We therefore construe the claim term "porcine circovirus type II" to be "a pathogenic pig virus having a circular genome that is at about 96% or more homologous with the four sequences disclosed in the present specification, and about 76% or less homologous with the PK/15 sequence." Strains that fit this definition would be expected to have strong serological similarity and cross-hybridize to the deposited strains under high stringency conditions. As such, limiting the claim scope according to these properties is not inconsistent with the other descriptive language in the specification.

"ORFs 1-13"

The district court's claim construction of ORFs 1-13 defines the claim scope as consisting of the DNA sequence of the thirteen ORFs enumerated in Example 13 of the patent specification as those ORFs apply to SEQ ID 4. Merial argues that the term should instead read on any translatable length of DNA between a start and stop codon in the PCV-2 gene sequence. Although the district court is correct that the disclosed ORFs define the claim term, the court erred in confining the scope of the term to the precise limits of the representative ORFs listed in Example 13, and the exact DNA sequence of SEQ ID 4.

The ORFs listed in Example 13 are identified as corresponding to one representative PCV-2 sequence, designated in the patent as SEQ ID 4. Although the patent explains that the listed ORFs are identical for some of the deposited strains of PCV-2, it also identifies some variation. The specification explains that the ORFs listed in the table are representative, and one of skill in the art would understand that slight natural variation is to be expected. Indeed, limiting the construction of the term to the exact ORF sequences of SEQ ID 4 would even exclude from the claimed ORFs two of the four sequenced strains of PCV-2, the ORF variations for which sequences are expressly disclosed following the table in Example 13. Thus, we hold that the district court's construction is improperly narrow in scope.

We reject the dissent's position that the specification limits "ORFs 1-13" to the ORFs of the four sequenced strains. The discussion in Example 13, which explains that the limits of ORFs 1 to 13 are "identical" for certain sequenced strains (and not for others), strongly implies that the term "ORFs 1-13" does not refer to a specifically

defined list of limits, but instead contemplates the potential for variation in any given strain of PCV-2. Furthermore, the specification describes the analysis set forth in Example 13 as "representative of the other circovirus strains associated with the multi-systemic wasting syndrome." We have already construed that set of circovirus strains to be broader than just the four sequenced strains, so it would be incongruous to selectively impose the narrower construction here, as the dissent suggests.

We note that because isolates of the same viral type will have essentially the same proteins, they will have the same number of ORFs. The ORFs will be approximately the same size and located in the same relative regions of the genome. By identifying the thirteen ORFs of representative sequence SEQ ID 4, the specification purports to disclose to one of skill in the art the expected ORFs of all PCV-2 isolates. Thus a broader claim construction that allows for some variation in the precise limits of the ORFs and of the underlying DNA sequence is consistent with the expectations of a skilled artisan reading the patent disclosure.

Thus the term ORFs 1-13 is properly construed as "lengths of translatable DNA between pairs of start and stop codons, corresponding to the 13 ORFs identified in the patent specification." ORFs of some PCV-2 strains may not have limits 100% identical to the thirteen illustrated in the patent, but one of skill in the art would readily recognize those ORFs as corresponding to ORFs identified in the patent. Indeed, ORFs 1-13 could correspond to ORFs in other circoviruses, or even other species, as indicated by the examiner's initial rejection of the claim. It is the "of porcine circovirus type II" limitation, rather than Example 13, that confines the claim scope to ORFs of PCV-2.

"Specific to PCV-2 and Not Specific to PCV-1"

The parties below could not agree on what terms of claim 32 were disputed, and the district court decided to construe the claim in its entirety. The district court construed claim 32 to mean "an isolated DNA molecule that includes, but is not necessarily limited to, a DNA sequence which codes for an immunodominant region of a protein, wherein the sequence is from the genome of a PCV-2 circovirus, and not from the genome of a PCV-1 circovirus." The district court explained that due to the "comprising" transition term, the claim may read on molecules that contain sequences that encode epitopes common to PCV-1 and PCV-2, as long as the molecule contains at least one sequence that encodes an epitope unique to PCV-2. We see no error in this construction, and it appears that at the time of the *Markman* hearing, Merial did not see any either.

Merial challenges this construction on appeal because in the district court's subsequent infringement analysis, the court explained that the part of the claim construction specifying that the sequence be "from" the genome of a PCV-2 circovirus, etc., excluded sequences that were physically derived from a non-PCV-2 source. Merial argues that such a manufacturing requirement has no place in a proper analysis of this claim, and is inconsistent with the district court's otherwise correct claim construction. We agree. For purposes of our review of the district court's opinion, we focus our analysis on the term "specific to" in claim 32, since it appears that this term is the hook for the requirement that the sequence be unique to and derived from PCV-2.

As Intervet explains, the term "specific to" is a specialized term of art in immunology that typically refers to

one structure's proclivity for binding to another structure. For example, antibodies will attack a viral antigen if paratopes of those antibodies are "specific to" an epitope in the viral antigen. The specialized definition of this term does not make sense in the context of claim 32, however, because the claimed epitope is not described as binding to porcine circoviruses; it is described as located within a porcine circovirus. The epitope is thus bound by antibodies that are "specific to" PCV-2. In light of the patent description and a general understanding of the relevant art, the claim would be understood by one of skill in the art to be using the term "specific to" in a colloquial or non-technical sense. *Cf. Intervet, Inc. v. Merial Ltd.*, No. 1:06-cv-00658 (D.D.C. Nov. 28, 2007) (claim construction order at 21). As construed, a nucleotide sequence encoding an epitope that is specific to PCV-2 and not specific to PCV-1, as that term is used in claim 32, is a nucleotide sequence that encodes part of a polypeptide sequence of PCV-2, but not part of a polypeptide sequence of PCV-1. More specifically, it encodes at least one epitope found on the PCV-2 virus, but not found on the PCV-1 virus.

The district court found that Intervet's vaccine could not have contained a sequence encoding an epitope specific to PCV-2 because the sequence was derived from a non-PCV-2 source. This analysis may be mooted by our reversal of the district court's claim construction of "PCV-2", since it is no longer clear that the source of the sequence in Intervet's product is not PCV-2. Nevertheless, to the extent that the district court's application of its claim construction requires that the encoded epitope be unique to PCV-2 among all possible antigens, it is erroneous. If the term "specific to PCV-2" meant that the epitope must be found only on PCV-2 and no other antigen, then the subsequent limitation "and not specific to PCV-

1" would be redundant. Thus an infringing epitope may be common to PCV-2 and some other antigen, as long as it is not also common to PCV-1. Whether one isolates the sequence directly from a PCV-2 virus or engineers a sequence obtained from another source such that it encodes a PCV-2 epitope makes no difference to the proper application of the district court's otherwise correct claim construction.

Accordingly, we reverse the district court's claim constructions of the terms "porcine circovirus type II" and "ORFs 1-13," clarify the proper interpretation of the construction of the term "specific to PCV-2 and not specific to PCV-1," and remand the question of infringement for a determination consistent with the claim constructions articulated herein.

Doctrine of Equivalents

The district court found that prosecution history estoppel precluded Merial from invoking the doctrine of equivalents. Merial was thus estopped from arguing that the accused PCV strain was equivalent to the claimed "porcine circovirus type II," as that term was construed by the district court.[5] The district court erred, however, in applying controlling Federal Circuit and Supreme Court law to the prosecution history of the '601 patent. As a result, the scope of the district court's bar on Merial's ability to invoke the doctrine of equivalents was overly broad.

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[5] Because we are reversing the judgment of literal infringement, it may not be necessary for the district court to reach the doctrine of equivalents claim, but we are addressing the issue in the event that the district court on remand finds it necessary to decide.

Whether prosecution history estoppel applies to a particular argument, and thus whether the doctrine of equivalents is available for a particular claim limitation, is a question of law. *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1354 (Fed. Cir. 1998); *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1460 (Fed. Cir. 1998) (en banc). Where an amendment narrows the scope of the claims, and that amendment is adopted for a substantial reason related to patentability, the amendment gives rise to a presumption of surrender for all equivalents that reside in "the territory between the original claim and the amended claim." *Festo Corp. v Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740 (2002) (*Festo VIII*). This presumption can be overcome by showing that "at the time of the amendment one skilled in the art could not reasonably be expected to have drafted a claim that would have literally encompassed the alleged equivalent." *Id.* at 741. One way to make this showing is to demonstrate that "the rationale underlying the narrowing amendment bore no more than a tangential relation to the equivalent in question." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1368 (Fed. Cir. 2003) (en banc) (*Festo IX*). Although there is no hard-and-fast test for what is and what is not a tangential relation, it is clear that an amendment made to avoid prior art that contains the equivalent in question is not tangential. *See Pioneer Magnetics, Inc. v. Micro Linear Corp.*, 330 F.3d 1352, 1357 (Fed. Cir. 2003).

The applicability of prosecution history estoppel does not completely bar the benefit of the doctrine of equivalents from all litigation related to the amended claim. *See Festo VIII*, 535 U.S. at 737-38 ("There is no reason why a narrowing amendment should be deemed to relinquish equivalents . . . beyond a fair interpretation of what was surrendered.") The scope of the estoppel must fit the

nature of the narrowing amendment. A district court must look to the specifics of the amendment and the rejection that provoked the amendment to determine whether estoppel precludes the particular doctrine of equivalents argument being made.

Merial's independent claim 9 as originally drafted read, "9. A vector comprising an isolated DNA molecule comprising a sequence selected from the group consisting of ORFs 1-13." The examiner rejected this claim, noting that for purposes of the rejection "[t]he ORFs are assumed to be derived from porcine circovirus, but as written, the claims could encompass ORFs from any organism." The claim was then rejected in view of ORFs from PK/15. The inventors disagreed that these ORFs could be derived from any other organism, and argued that the specification defined ORFs 1-13 based on the limits of the ORFs in the PCV-2 genome. Nevertheless, the claim was amended to add the limitation that the ORFs were "of porcine circovirus type II". The examiner then allowed the claim.

We agree with the district court that this amendment was a narrowing amendment, despite Merial's arguments that it was merely clarifying. As noted in the patent specification, four of the thirteen claimed ORFs are present in the "type I" circovirus. The original claim only required that a vector comprise a nucleotide sequence comprising one of the thirteen ORFs. Thus, the claim as originally written read on ORFs of PCV-1, and was properly rejected over PK/15. We therefore also agree with the district court that the amendment was substantially related to patentability.

The amendment thus raises a presumption of surrender for all equivalents that reside in the territory between the identified ORFs of PCV-2 and ORFs of PCV-1, as well

as corresponding ORFs, if any, for any non-porcine organism. Merial is thus estopped from arguing that ORFs of pathogenic circoviruses found in other organisms are equivalent to ORFs of PCV-2. It is also estopped from arguing that ORFs of a pathogenic strain of PCV-1 are equivalent to ORFs of PCV-2, despite the strain having strong homology with PK/15 and weak homology with the representative strains disclosed in the patent. Merial is not, however, estopped from arguing that a pathogenic porcine viral sequence with over 99% nucleotide homology with one of the five representative strains is equivalent to that strain.[6] Such a draconian preclusion would be beyond a fair interpretation of what was surrendered. *Cf. Festo VIII*, 535 U.S. at 737-38. The rationale for the amendment was to narrow the claimed universe of ORFs down to those of PCV-2, and bore only a tangential relation to the question of which DNA sequences are and are not properly characterized as PCV-2. *Cf. Festo IX*, 344 F.3d at 1369.

The district court thus erred in finding that prosecution history estoppel precluded Merial from arguing that the accused product is equivalent to one of the exemplary embodiments of the asserted claim. The district court is thus instructed on remand to compare the accused product with the claims as construed herein for a determination of infringement literally or pursuant to the doctrine of equivalents, if applicable.

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[6] Merial is thus not estopped from arguing that such a sequence would infringe even though it did not meet the exact homology limitations required for literal infringement of the claims as construed by this court.

CONCLUSION

The district court erred in construing the disputed claims of the patent in suit and in barring the doctrine of equivalents from its infringement analysis. Accordingly, we reverse the district court's claim construction, vacate the entry of summary judgment of noninfringement, and remand to the district court with instructions to determine, consistent with the analysis in this opinion, whether the accused product infringes the asserted claims of the '601 patent.

REVERSED-IN-PART, VACATED-IN-PART, AND REMANDED

United States Court of Appeals for the Federal Circuit

INTERVET INC.,
Plaintiff-Appellee,

v.

MERIAL LIMITED AND MERIAL SAS,
Defendants-Appellants.

2009-1568

Appeal from the United States District Court for the District of Columbia in case no. 06-CV-0658, Judge Henry H. Kennedy, Jr.

DYK, *Circuit Judge*, concurring-in-part and dissenting-in-part.

I agree with the majority's construction of claim 32 of U.S. Patent No. 6,368,601 ("the '601 patent"), but as discussed below, I disagree with its construction of claim 9. I write separately primarily to make clear that in construing the claims, we are not deciding that the claims as construed are limited to patentable subject matter. As we noted in *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), we do not take validity into account in construing claims, unless "the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous." *Id.* at 1327 (quoting *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 911 (Fed.

Cir. 2004) (quotation marks omitted)). That is not the case here.

At least claim 32 of the '601 patent raises substantial issues of patentable subject matter under 35 U.S.C. § 101. That claim is not limited to the use of a particular isolated DNA molecule in a vaccine or other application. Rather, it broadly encompasses "[a]n *isolated DNA molecule* comprising a nucleotide sequence encoding an epitope which is specific to PCV-2 and not specific to PCV-1." '601 patent col.28 ll.40-42 (emphasis added). Neither the district court nor the parties provided a precise definition of "isolated" DNA. In order to analyze the DNA or use it for applications (for example, the production of vaccines), DNA must be extracted from the cell of the living organism and separated from other cell components, such as RNA, protein, lipids, or in the case of plasmid DNA isolation, from chromosomal DNA. *See generally*, Peter B. Kaufman et al., *Handbook of Molecular and Cellular Methods in Biology and Medicine* 1-26 (1995). DNA "isolation" applies generally to the process of extracting DNA from a cell for purposes of genetic analysis. *See* James D. Watson et al., *Molecular Biology of the Gene* 740 (6th ed. 2008); *see also* Kaufman et al., *supra*, at 1-2. Isolation also encompasses techniques for selective amplification or cloning of such fragments, which allows for a large number of fragments to be available for analysis and sequencing. *See* Watson et al., *supra*, at 746. The '601 patent indicates that the isolation of the genomic DNA of the viral strains was performed by a method well known in the art. *See* '601 patent col.10 l.5-col.11 l.43.

The majority interprets "PCV-2" to mean "a pathogenic pig virus having a circular genome that is at about 96% or more homologous with the four sequences disclosed in the present specification, and about 76% or less homologous with the PK/15 sequence," Majority Op. at 9,

reversing the district court's construction limiting PCV-2 to the five viral strains specifically disclosed in the '601 patent. Additionally, the majority construes "specific to PCV-2 and not specific to PCV-1" to read on molecules that contain sequences that encode epitopes[1] common to PCV-1 and PCV-2, as long as the molecule contains at least one sequence that encodes an epitope unique to PCV-2. *Id.* at 11-12. Patent claim 32 reads on an isolated DNA molecule that comprises a nucleotide sequence that encodes an epitope unique to PCV-2, which is defined with respect to its homology with the known PCV-1 virus. Thus, under the majority's claim construction, claim 32 covers DNA sequences that were not in fact isolated by the inventor and are distinct from the five isolated strains disclosed in the '601 patent.

The question is whether the isolated DNA molecule, separate from any applications associated with the isolated nucleotide sequence (for example, the production of a vaccine) is patentable subject matter. Neither the Supreme Court nor this court has directly decided the issue of the patentability of isolated DNA molecules. Although we have upheld the validity of several gene patents, *see, e.g.*, *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995); *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993); *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.3d 1200 (Fed. Cir. 1991), none of our cases directly addresses the question of whether such patents encompass patentable subject matter under 35 U.S.C. § 101. Although the U.S. Patent and Trademark Office ("PTO") believes that at least some of these patents satisfy section 101, *see* Utility Examina-

[1] An epitope is an immunodominant region of a protein, meaning it is the part of an antigen that is recognized by antibodies of the immune system.

tion Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001),[2] thus far the question has evaded judicial review.

I think that such patents do in fact raise serious questions of patentable subject matter. The Supreme Court's recent decision in *Bilski v. Kappos* has reaffirmed that "laws of nature, physical phenomena, and abstract ideas" are not patentable. No. 08-964, slip op. at 5 (U.S. June 28, 2010) (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980)); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). Just as the patentability of abstract ideas would preempt others from using ideas that are in the public domain, *see Bilski*, slip op. at 13, so too would allowing the patenting of naturally occurring substances preempt the use by others of substances that should be freely available to the public. Thus, "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity." *Chakrabarty*, 447 U.S. at 309. These aspects are properly conceptualized as representing a public domain, "free to

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[2] In response to comments urging the PTO not to issue patents for genes on the ground that genes are products of nature, the PTO remarked:

> An isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised gene is eligible for a patent as a composition of matter or as an article of manufacture because that DNA molecule does not occur in that isolated form in nature, or (2) synthetic DNA preparations are eligible for patents because their purified state is different from the naturally occurring compound.

66 Fed. Reg. at 1093.

all men and reserved exclusively to none." *Id.* (quoting *Funk Bros.*, 333 U.S. at 130) (quotation mark omitted).

In *Funk Brothers*, the Court considered the patentability of a mixture of several naturally-occurring species of bacteria. 333 U.S. at 128-31. The patented product was a mixture of bacteria used in agricultural processes, enabling plants to draw nitrogen from the air and convert it for usage. The inventor discovered that certain strains of the bacteria were effective in combination with one another, and contrary to existing assumptions, did not exert mutually inhibitive effects on each other. The Court held that the invention was not patentable subject matter. *Id.* at 131. The inventor "did not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable." *Id.* at 130. The Court furthermore noted:

> The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.

Id.

In *Chakrabarty*, the Court considered whether a human-made microorganism is patentable subject matter under section 101. 447 U.S. at 305. The microorganism in question was a bacterium that had been genetically engineered to break down crude oil. In concluding that the man-made bacteria was patentable, the Court ob-

served that the claim "is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter." *Id.* at 309. The Court went on to distinguish *Funk Brothers* on the ground that the *Chakrabarty* bacterium possessed "*markedly different characteristics from any found in nature*. . . . His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101." *Id.* at 310 (emphasis added).

Thus, it appears that in order for a product of nature to satisfy section 101, it must be qualitatively different from the product occurring in nature, with "markedly different characteristics from any found in nature." It is far from clear that an "isolated" DNA sequence is qualitatively different from the product occurring in nature such that it would pass the test laid out in *Funk Brothers* and *Chakrabarty*. The mere fact that such a DNA molecule does not occur in isolated form in nature does not, by itself, answer the question. It would be difficult to argue, for instance, that one could patent the leaves of a plant merely because the leaves do not occur in nature in their isolated form.

Finally, I disagree with the majority with respect to its construction of "ORFs 1-13" in claim 9.[3] Merial argues, and the majority appears to accept, the proposition that one of ordinary skill in the art would read the phrase "ORFs 1-13" to read on any translatable length of DNA between a start and stop codon in the PCV-2 sequence that could encode for a protein greater than twenty amino

[3] An Open Reading Frame ("ORF") is a region or length of DNA that contains a sequence of nucleotides that contains the instructions for making proteins. All ORFs begin and end with a set of three nucleotides known respectively as a start and stop codon.

acids in size. In contrast, the district court concluded that the plain language of the claims indicated that ORFs 1-13 were limited to the ORFs in the disclosed isolates.[4]

I agree with the district court that the phrase must be limited to the specific DNA sequences defined as ORFs 1-13 in the '601 patent based on the intrinsic evidence. The majority holds that the district court's construction is improperly narrow in scope because "limiting the construction of the term to the exact ORF sequences of SEQ ID 4 would even exclude from the claimed ORFs two of the four sequenced strains of PCV-2." Majority Op. at 10. I disagree. The specification appears to specifically define "ORFs 1-13" to include the ORFs from all four of the

[4] It is unclear whether the district court's claim construction limited "ORFs 1-13" to the relevant ORFs in Imp. 1010, or whether the phrase also encompasses ORFs 1-13 of the other isolates disclosed in the patent, namely, Imp. 1011-48121, Imp. 1011-48284, and Imp. 999. The court's infringement determination is also unclear. *See Intervet, Inc. v. Merial Ltd.*, 643 F. Supp. 2d 97, 103 (D.D.C. 2009) ("Example 13, however, also states that the positions of the start and end of each ORF refer to the sequence presented in figure 4. Figure 4 contains the precise DNA sequence of one of the five listed strains and thus Example 13, while it does not include the specific DNA sequence of each ORF, refers to a figure from which those specific DNA sequences can be determined. Given this, the Court declines to read the language 'specific DNA sequence' out of its claim construction, and therefore concludes that Intervet's vaccine does not contain one of ORFs 1-13.").

sequenced strains, not just Imp. 1010,[5] represented by SEQ ID 4. The specification provides:

> It was possible to detect 13 open reading frames (or ORFs) of a size greater than 20 amino acids on this sequence (circular genome). *These 13 ORFs are the following*:

'601 patent col.13 ll.33-34 (emphasis added). The specification then proceeds to detail the ORF sizes and stop and start codons for the Imp. 1010 isolate in table form, and describes the stop and start codons for the other three isolates by reference to Imp. 1010:

> The positions of the start and end of each ORF refer to the sequence presented in FIG. No. 4 (SEQ ID No. 4), of the genome of strain 1010. The limits of ORFs 1 to 13 are identical for strain 999. They are also identical for strains 1011-48121 and 1011-48285, except for the ORFs 3 and 13:
>
> ORF3 1432-1549, sense, 108 nt, 35aa
>
> ORF1,3 314-1377, antisense, 705 nt, 234 aa.

Id. col.13 ll.53-61. Thus, "ORFs 1-13" is properly read to include the relevant ORFs on all of the disclosed isolates, because a description of those ORFs follows the assertion that "[t]hese 13 ORFs are the following." *Id.* col.13 ll.33-34. Because the patentee acted as his "own lexicographer and clearly set forth a definition of the disputed claim term," *Edward Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1329 (Fed. Cir. 2009), the definition in the specification controls, *see Phillips*, 415 F.3d at 1321. In my view,

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[5] The "Imp." designation, an abbreviation for "imported," is a tracking number assigned by the inventors to their pig tissue samples and to any virus they isolated from that tissue.

claim 9 is not literally infringed, and I would also hold that it is not infringed under the doctrine of equivalents.